

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
29 March 2007 (29.03.2007)

PCT

(10) International Publication Number  
WO 2007/035444 A2

(51) International Patent Classification:  
*A61B 5/103* (2006.01)      *A61B 5/00* (2006.01)

(21) International Application Number:  
PCT/US2006/035927

(22) International Filing Date:  
15 September 2006 (15.09.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/717,490      15 September 2005 (15.09.2005) US

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

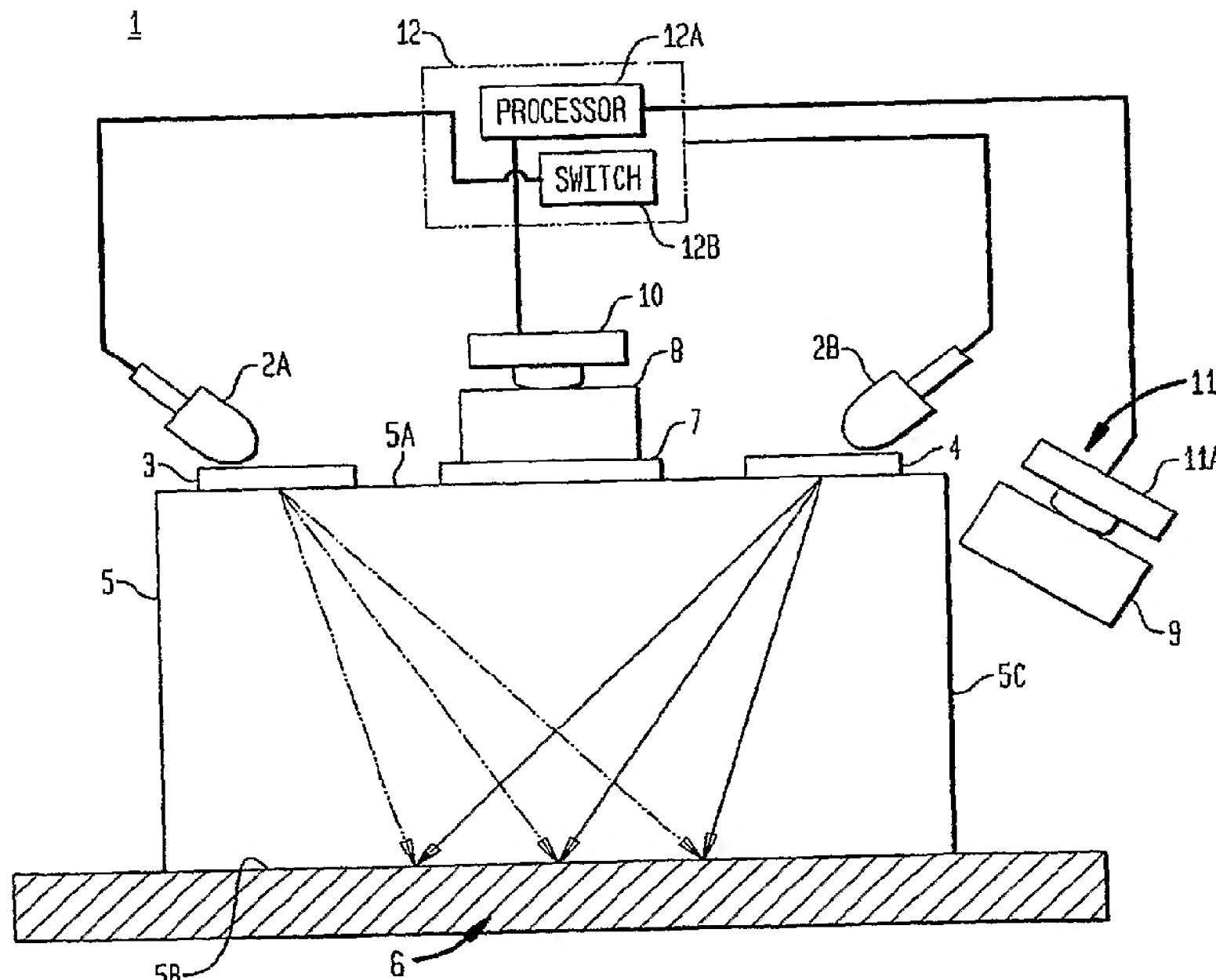
(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: SKIN OPTICAL CHARACTERIZATION DEVICE



(57) Abstract: The present invention is generally directed to dermatological devices and methods in which one or more skin characteristics, such as the melanin index, are determined by analyzing radiation backscattered from a skin region illuminated by at least one, and preferably, two or more wavelengths, e.g., in a range of about 600 nm to about 900 nm. In many embodiments, the radiation is coupled to the skin via a waveguide, and an optical sensor is employed to ascertain contact between the waveguide (e.g., a waveguide surface adapted for contact with the skin) and the skin.

WO 2007/035444 A2



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## SKIN OPTICAL CHARACTERIZATION DEVICE

### CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application  
5 Serial No. 60/717,490 filed on September 15, 2005, which is herein incorporated  
by reference in its entirety.

### BACKGROUND

The present invention relates generally to diagnostic and therapeutic  
10 dermatological devices and methods that measure physical characteristics of  
tissue, such as, the skin.

Dermatological devices are used to improve a variety of skin conditions,  
such as removal of unwanted hair, skin rejuvenation, removal of vascular lesions,  
15 acne treatment, treatment of cellulite, pigmented lesions and psoriasis, tattoo  
removal, treatment of skin and other cancers, etc. Many of these devices typically  
target a chromophore in the tissue of the subject under treatment. Depending on  
the procedure, such a chromophore may be, for example, melanin, hemoglobin,  
lipid, water, or pigment of a tattoo.

20

Optimal use of these devices depends, at least in part, on accurate  
identification of the subject's skin pigmentation so that proper treatment  
parameters can be used. However, commonly used methods of skin typing are  
not generally based on actual measurements of the chromophores of interest, such  
25 as the amount of melanin in the skin. For example, the commonly used  
Fitzpatrick skin type scale, which ranges from very fair (skin type I) to very dark  
(skin type VI), is based solely on a person's complexion and response to sun  
exposure. In addition, such conventional skin typing methods do not take into  
account variations in the concentration of a chromophore in different parts of an  
30 individual's skin. For example, although different parts of an individual's skin  
can exhibit different melanin concentrations, the Fitzpatrick scale provides only a  
single skin type for that individual. As such, the use of such conventional skin  
typing methods may result in complications during treatment, such as burns,  
scars, or ineffective treatment.

Therefore, a need exists for dermatological and other devices and methods that can accurately and efficiently determine physical characteristics of a person's skin, such as, for example, skin melanin optical density (MOD), blood content, 5 collagen content, and/or hydration. In addition, improved safety mechanisms are needed for dermatological devices so that they can be used for non-professional uses, such as home use.

### **SUMMARY OF THE INVENTION**

10 In one aspect, the present invention provides a dermatological device for determining a physical characteristic of a portion of tissue that comprises a radiation source assembly configured to generate radiation having at least a first wavelength and a waveguide coupled to that source assembly for directing the radiation from the source to the tissue portion, where the waveguide has a surface 15 configured to irradiate the tissue portion with the radiation. The device further includes a detector coupled to the waveguide and configured to detect radiation from the source, where the detector generates signals indicative of the level of radiation detected. A processor in communication with the detector processes the signals and calculates a physical characteristic of the tissue region. The detector 20 can be configured to detect the radiation from the source after the portion of the tissue has been irradiated with the radiation from the source.

In a related aspect, the skin characteristic can be, e.g., any of melanin index, collagen content, diffusion or erythema measurement.

25 In another aspect, the radiation source assembly can include two or more radiation sources. For example, the first radiation source can produce radiation having a first (or first wavelength band) wavelength and a second radiation source can produce radiation having a second wavelength (or second wavelength band). 30 Alternatively, the radiation source assembly can include a single radiation source. The radiation source can produce radiation of more than one wavelength (i.e., radiation of a first wavelength and also radiation of a second wavelength), or radiation source assembly can be configured to generate radiation having two or more, or three or more wavelengths. The first and/or second wavelength can be

selected from a range of about 350 nm to about 1200 nm, or from a range of about 600 nm to about 900 nm. In some embodiments, the radiation source assembly can include at least one of a light emitting diode (LED), a bi-color LED, a tunable radiation source, and/or a laser radiation source. The term "wavelength" as used 5 herein is not necessarily limited to monochromatic light but rather can also define a line or band of wavelengths, depending upon the nature of the light source.

In another aspect, the device can further comprise a contact sensor indicating whether the surface of the optical waveguide is in contact with the skin. 10 By way of example, the contact sensor can be configured to detect a level of the radiation at a wavelength generated by the source. In some embodiments wherein the radiation source assembly is configured to generate radiation having two or more wavelengths, the contact sensor can be configured to detect a level of the radiation at two or more of those wavelengths.

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In a related aspect, in the above device, the contact sensor can be configured to send a signal to the processor indicating that the surface of the waveguide is not in contact with the tissue. For example, the contact sensor can send a signal when the contact sensor detects that the detected radiation level is 20 below or above a threshold. The contact sensor can be optically coupled to the waveguide along a boundary, wherein the waveguide is configured to totally internally reflect the radiation along that boundary when the surface is not in contact with the tissue. Alternatively, the contact sensor can be optically coupled to the waveguide along a boundary, wherein the waveguide is configured to not totally internally reflect the radiation along that boundary when the surface is not 25 in contact with the tissue.

In another aspect, the contact sensor can be configured to send a signal to the processor indicating that the surface of the waveguide is in contact with the tissue. For example, the contact sensor can detect that the detected radiation level 30 is above or below a threshold. The contact sensor can be optically coupled to the waveguide along a boundary, wherein the waveguide is configured to not totally internally reflect the radiation along that boundary when the surface is in contact with the tissue. Alternatively, the contact sensor can be optically coupled to the

waveguide along a boundary, wherein the waveguide is configured to totally internally reflect the radiation along that boundary when the surface is in contact with the tissue.

5 In another aspect, the device can further comprise two polarizers, one of which can be configured to filter radiation of a first polarity from the radiation source assembly and the other can be configured to filter radiation of a second polarity entering the contact sensor and/or entering the detector. The device can include a filter disposed between the contact sensor and the waveguide and/or  
10 between the waveguide and the detector.

In another aspect, the device can further comprise a controller coupled to the radiation source assembly. The controller can be configured to activate the radiation source assembly to produce radiation of different wavelengths at  
15 different times.

In another aspect, the waveguide can be formed of a material having an index of refraction in a range of about 1.4 to about 2.5. In some embodiments, the waveguide is an optical fiber. The device can further include at least one  
20 additional waveguide coupled to the source assembly. In some cases, that additional waveguide can be an optical fiber.

In another aspect, the invention discloses a dermatological device for determining a physical characteristic of a portion of tissue that comprises a  
25 radiation source assembly configured to generate radiation having first and second wavelengths, and a waveguide coupled to the source assembly for directing the radiation from the source to a portion of the tissue, and having a surface configured to irradiate that tissue portion with the radiation. The waveguide surface can be adapted for contact with the tissue and can inhibit transmission of  
30 radiation in absence of skin contact by total internal reflection of radiation reflected by a sidewall thereto. The device can further include a detector coupled to the waveguide and configured to detect radiation from the source, wherein the detector can generate signals indicative of the level of radiation detected. The detector can be configured to detect the radiation from the source after the portion

of the tissue has been irradiated with the radiation from the source. A processor in communication with the detector can process the signals and calculate a physical characteristic of the tissue portion (e.g., a skin portion). In other words, the processor can determine a tissue (e.g., skin) characteristic based on the  
5 detector output.

In a related aspect, in the above device, a contact sensor optically coupled to the waveguide along a boundary can be configured to detect a level of the radiation transmitted through that boundary to determine whether said waveguide  
10 surface is in contact with the tissue..

In a related aspect, the first and second wavelengths can be in a range of about 300 nm to about 1200 nm, about 600 nm to about 900 nm, or about 630 nm to about 730 nm. For example, the first wavelength can be approximately 645  
15 nm, or approximately 700 nm. In some embodiments, the first wavelength is approximately 645 nm and the second wavelength is approximately 700 nm.

In another related aspect, the device can further comprise a feedback mechanism in communication with the sensor and the source, wherein the  
20 feedback mechanism is capable of inhibiting activation of the source when the sensor indicates lack of optical contact between the waveguide and the source, and is capable of activating the source when the sensor indicates optical contact.

In another aspect, the invention provides a dermatological device with at  
25 least one radiation source, a waveguide optically coupled to the radiation source to transmit radiation from the source to the skin, the waveguide having two opposed surfaces and a sidewall extending between the surfaces. The device can further include a detector coupled to the waveguide to detect at least a portion of radiation backscattered from a skin region illuminated by the source radiation, and  
30 an optical contact sensor optically coupled to the sidewall, the sensor determining whether the waveguide is in contact with the skin based on detection of backscattered radiation leaking through the sidewall.

In yet another aspect, a dermatological device is disclosed comprising a radiation source assembly, a first waveguide having a proximal end adapted to receive radiation from the radiation source assembly and a distal end adapted to transmit radiation to a tissue, a second waveguide having a distal end adapted to receive backscattered radiation from the first waveguide and a proximal end adapted to transmit the backscattered radiation. The device can further include a detector optically coupled to the second waveguide and configured to measure a physical characteristic of the tissue; and a processor electrically coupled to the detector and configured to receive a signal from the detector corresponding to the backscattered radiation. The processor is configured to determine a physical characteristic of the tissue based on the backscattered radiation that is detected. The device can further include a means for coupling the backscattered radiation exiting from the proximal end to the detector, such as a beamsplitter. The radiation source assembly is capable of generating radiation at two or more wavelengths in a range of about 350 nm to about 1200 nm, or about 600 nm to about 900 nm. The device can further comprise additional waveguides, such as optical fibers.

In another aspect, the invention provides a dermatological device that comprises at least one source of radiation, an optical fiber receiving radiation from the source at a proximal end and applying the radiation to a skin region at a distal end, another optical fiber coupled at a distal end to skin at another region separated from the illuminated region by a skin segment so as to receive at least a portion of the applied radiation after transmission through that segment, a detector optically coupled to a proximal end of the another optical fiber to detect at least a portion of the transmitted radiation received by that fiber, the detector generating a signal indicative of an intensity of the received radiation, and a processor operating on the detector signal to determine a skin characteristic.

In another aspect, a method of determining a characteristic of tissue is disclosed that comprises the steps of applying radiation of first and second wavelengths from a waveguide to the tissue; detecting at least a portion of radiation of the first and second wavelengths backscattered from the tissue; generating at least one signal indicative of an intensity of the backscattered

radiation, and processing the at least one signal to calculate a characteristic of the skin region. The step of applying radiation can further include applying radiation at a plurality of wavelengths selected from a range of about 350 nm to about 1200 nm, or in a range of about 600 nm to about 900 nm, to the skin. In addition,  
5 optical contact between the waveguide and the skin region can be detected. Contact of the waveguide with the tissue can be sensed by detecting a level of the backscattered radiation. The method can further include reducing ambient radiation to prevent its detection by the detector. In some embodiments, the method further can include reducing radiation having a first polarity prior to  
10 detection; and detecting radiation having a second polarity.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

FIGURE 1A is a schematic side view of a dermatological device in accordance with one embodiment of the invention;

15 FIGURE 1B schematically shows that in the absence of contact between a waveguide of the device of FIGURE 1A and the skin, a substantial number of radiation rays backscattered from the skin into the waveguide are totally internally reflected at the waveguide's sidewall to which an optical sensor is optically coupled, thus resulting in a low detection signal by the sensor;  
20

25 FIGURE 1C schematically shows that in the presence of contact between the waveguide of device of FIGURE 1A and the skin, a substantial number of radiation rays backscattered from the skin into the waveguide to be incident on a sidewall of the waveguide to which an optical sensor is coupled are transmitted through the sidewall to reach the sensor, thus resulting a sensor signal above a threshold that indicates contact;

30 FIGURE 1D schematically shows that the detector of an optical sensor coupled to a sidewall of a waveguide of the device of FIGURE 1A is positioned relative to the sidewall such that a central ray corresponding to the detector's viewing solid angle makes an angle  $\phi$  relative to the sidewall selected to ensure that in the absence of contact between the waveguide and the skin, the radiation rays backscattered from the skin into the waveguide are substantially inhibited

from reaching the detector and, in presence of contact, some of those rays exit the sidewall to reach the detector;

FIGURE 1E schematically depicts a skin portion comprising an epidermis layer, a dermis layer and an epidermis/dermis junction exhibiting a high concentration of melanin;

FIGURE 1F is a schematic diagram of rays of radiation entering a waveguide from the air at various angles;

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FIGURE 1G is a schematic diagram of rays of radiation entering a waveguide from skin tissue at various angles;

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FIGURE 2 depicts the emission spectra associated with two exemplary LEDs suitable for use in some embodiments of the invention;

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FIGURE 3 depicts trigger signals applied to the LEDs forming radiation sources in an embodiment of the invention as well as the backscattered signals detected for illumination of a skin portion with radiation generated by those LEDs;

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FIGURE 4 shows the signal sensitivity of an exemplary, illustrative device according to an embodiment of the invention for measuring the melanin index as a function of tilt angle relative to the skin under observation;

30

FIGURE 5 shows the signal sensitivity of an exemplary, illustrative device according to an embodiment of the invention for measuring the melanin index as a function of the thickness of an air gap between a surface of a device adapted for contact with the skin and a skin portion under observation;

FIGURE 6 is a schematic side view of a dermatological device according to another embodiment of the invention that employs a single radiation source capable of generating radiation at two or more wavelengths in a wavelength range of interest;

FIGURE 7A schematically depicts a dermatological device in accordance with another embodiment of the invention that utilizes a waveguide having a reflective sidewall for coupling radiation from a source into the skin;

5

FIGURE 7B schematically shows that the reflective sidewall of the waveguide of the device of FIGURE 7A directs radiation received from the source to a surface of the waveguide adapted for contact with the skin such that in the absence of contact, the radiation is totally internally reflected from that 10 contact surface;

FIGURE 8A is a schematic side view of a dermatological device according to another embodiment of the invention that includes two radiation sources capable of generating radiation at different wavelengths and a waveguide 15 having reflective sidewalls for reflecting radiation from those sources to the skin;

FIGURE 8B is a schematic side view of a dermatological device in accordance with another embodiment of the invention that utilizes two radiation source whose radiation is reflected to the skin via reflective sidewalls of a 20 waveguide and further includes two detectors for detecting radiation backscattered from the illuminated skin;

FIGURE 9 schematically depicts a dermatological device in accordance with another embodiment of the invention that utilizes a radiation source to 25 couple radiation via a prism to the skin at one location and utilizes a detector optically coupled to the skin at another location to collect at least some of the radiation transmitted through the skin for measuring a characteristic of the skin, such as the melanin optical density;

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FIGURE 10 schematically depicts the use of the device of FIGURE 9 placed above and detecting the iris of a human eye;

FIGURE 11A schematically depicts a dermatological device in accordance with another embodiment of the invention that employs optical fibers for coupling radiation into the skin and for collecting radiation backscattered from the skin;

5 FIGURE 11B schematically depicts another embodiment of a dermatological device according to the teachings of the invention that employs one or more optical fibers for coupling radiation into the skin and an annular waveguide for collecting radiation that is backscattered from the skin;

10 FIGURE 11C is a perspective schematic view of an exemplary annular waveguide suitable for use in the device of FIGURE 11B;

15 FIGURE 11D is a perspective schematic view of an annular waveguide suitable for use in the device of FIGURE 11B, which comprises a plurality of optical fibers disposed in an annular enclosure;

20 FIGURE 11E is a schematic top view of a surface area of the skin illuminated by a radiation source of the device of FIGURE 11B as well as an area coupled to the annular waveguide of that device through which backscattered radiation is collected;

25 FIGURE 12 is a schematic side view of a device in accordance with another embodiment of the invention that employs an optical fiber for transmitting radiation received from a source at a proximal end thereof to the skin via its distal end;

30 FIGURE 13 schematically depicts another embodiment of a dermatological device according to the teachings of the invention that includes an optical fiber having a split end to provide an input port for receiving radiation from a source and output port for coupling backscattered radiation collected at its distal end to a detectors;

FIGURE 14 schematically depicts a dermatological device according to an embodiment of the invention having a treatment module and a diagnostic module, which is constructed in accordance with the teachings of the invention; and

5 FIGURE 15 schematically depicts a dermatological device according to an embodiment of the invention designed to provide both diagnostic and treatment capabilities in a compact enclosure.

### **DETAILED DESCRIPTION**

10 The present invention relates generally to diagnostic and/or therapeutic dermatological and other devices, as well as diagnostic and therapeutic methods, that determine one or more characteristics of the skin by analyzing radiation scattered by the skin in response to its illumination at at least one wavelength, and more preferably, at two or more wavelengths. In other aspects, the invention  
15 provides optical sensors for determining whether an optical element, such as a waveguide or treatment window through which radiation from a device is transmitted to the skin, is in contact with the skin.

FIGURE 1A schematically depicts a cross-sectional view of an exemplary  
20 dermatological device 1 in accordance with one embodiment of the invention that measures a physical property of tissue, the melanin optical density (“MOD”) of human skin in this particular embodiment. Device 1 includes two light sources 2A and 2B that generate radiation having different wavelengths selected to be sufficiently separate to provide two independent measures of the physical  
25 characteristic. Depending on the application, various wavelengths can be used. In this case, for the measurement of MOD, many different wavelengths can be selected, but the wavelengths preferably are in a range of about 600 nm to about 900 nm, though wavelengths in other ranges can also be employed. (The terms “light” and “radiation” are herein used interchangeably to refer to electromagnetic  
30 radiation within a desired spectral range. Unless otherwise specified, these terms are used as examples, and it should be understood that other forms of radiant energy can be used depending on the application, including acoustic energy, ultrasound, microwaves, infrared, visible light and other electromagnetic radiation.)

Generally, the separation of the wavelengths is selected so as to elicit a sufficient differential response at those wavelengths from a skin chromophore (e.g., melanin) so as to allow accurate measurements of that chromophore's concentration in the skin. By way of example, in this embodiment, source 2A generates radiation at a wavelength of about 645 nm, while source 2B generates radiation at a wavelength of about 700 nm. This choice of the wavelengths is particularly suited for measuring the skin melanin content, as it provides adequate differential response from melanin while minimizing optical interference from other skin components, such as blood or water.

A variety of coherent or incoherent radiation sources can be utilized as sources 2A and 2B. For example, in some embodiments, the sources 2A and 2B include light emitting diodes (LEDs) while in others, they can include laser diodes, lamps, etc. In still other embodiments, a single source can be used to produce both wavelengths of light by, for example, passing light from an incoherent source through one or more filters. Similarly, a single source could be used to provide radiation across one or more bands of radiation, while the desired wavelengths within the band are detected using sensors sensitive to those wavelengths.

The use of LEDs in this exemplary embodiment provides a number of advantages. For example, LEDs are typically low cost, compact and reliable radiation sources. Further, their light output can be controlled and modulated precisely. In addition, the profiles of their output radiation beams can be controlled, e.g., by utilizing molded lenses. It should, however, be understood that any other suitable radiation source can also be employed.

The light sources 2A and 2B are optically coupled to a waveguide 5 via a top surface 5A thereof such that at least a portion of the light generated by each source enters the waveguide for transmission to a subject's skin. Waveguides are well known in the art of optics, and generally refer to any optically transmissive medium that provides an optical path from a first location to a second location through the medium. As discussed in more detail below, the radiation entering

the waveguide is transmitted by the waveguide to a surface 5B thereof through which, upon contact of that surface with the skin, the radiation is transmitted to a skin region 6. A portion of the radiation illuminating the skin is specularly reflected by the skin surface, and another portion enters the skin.

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As the skin is a turbid medium, the radiation entering the skin undergoes multiple scattering and/or reflection events, which result in re-entry of some of the radiation back into the waveguide (that is, some of the radiation is backscattered into the waveguide). The waveguide 5 can advantageously function similarly to an optical integrating sphere to allow a substantially uniform illumination of a skin segment of interest, and can facilitate coupling of the backscattered radiation to a detector 10. The detector 10 is optically coupled to the surface 5A of the waveguide to receive at least a portion of the backscattered radiation that is coupled from the skin into the waveguide, via the waveguide's surface 5B. At least a portion of the backscattered radiation is coupled out of the waveguide through the surface 5A to be detected by the detector. A variety of optical radiation detectors known in the art can be employed. An example of such a detector includes a commercially available detector marketed by Hamatsu as serial number 56865-01.

10

As such, the waveguide can allow repeatable optical coupling between the device and the skin. As discussed in more detail below, poor coupling between the device and the skin can lead to inaccurate measurements due to dramatic changes in light coupling, transmission and diffusion. Furthermore, in device 1, the waveguide medium is a substance, in this case, sapphire or other suitable medium, such as fused silica or glass, that has an index of refraction sufficiently different than air to, as discussed in greater detail below, utilize the concept of total internal reflection to achieve the desired measurement of MOD. (However, as will be evident in additional embodiments described below, other media, including substances having an index of refraction close to that of air or even air itself, may be used as a waveguide. For example, a hollow reflective tube containing a fluid such as air or configured to secure a liquid, could be used as a waveguide in some embodiments.)

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Device 1 further includes polarizers 3 and 4, which have parallel polarization axes which are placed between the light sources 2A and 2B, respectively, and the surface 5A of the waveguide 5. Another polarizer 7, having a polarization axis perpendicular to that associated with polarizers 3 and 4, is

5 placed between detector 10 and the surface 5A of the waveguide 5. The purpose of the polarizers 3, 4 and 7 is to remove light reflected from the surface of the tissue and other surfaces and that does not, therefore, penetrate into the tissue.

This arrangement of polarizers ensures that the radiation that is specularly reflected from various interfaces (e.g., waveguide/air, waveguide/skin, air/skin, or

10 waveguide/lotion, air/lotion (in cases where lotion is applied to the skin)) is substantially inhibited from reaching the detector 10. Such specularly reflected radiation has the same (or at least substantially the same) polarization as that of the polarized radiation from the sources, and hence is blocked by the orthogonal polarizer coupled to the detector. The use of this arrangement of polarizers is

15 particularly advantageous in preventing the radiation that is specularly reflected from the skin surface from reaching the detector. The specularly reflected radiation does not penetrate the skin and hence it typically does not contain any information regarding the skin pigment of interest. Its blockage from the detector 10 increases the accuracy of the measurement. In contrast, the information

20 regarding the skin pigment of interest is carried mostly by the light that is diffusely backscattered by the dermis layer of the skin. As this diffusely scattered light exhibits random polarization, a portion of the light having the opposite polarization from the specularly reflected light can pass through the polarizer 7 to be detected by the detector 10. Thus, the light that reaches detector 10 is

25 predominately light that provides information about the physical characteristic being measured, in this case the MOD of the tissue.

In addition, device 1 contains a spectral filter 8 between polarizer 7 and detector 10. This filter passes the desired wavelengths emitted by sources 2A and

30 2B, but filters out other sources of radiation noise (e.g., ambient light and radiation from the treatment source), thereby enhancing the measurement sensitivity of the device.

With continued reference to FIGURE 1A, the device 1 further includes an optical contact sensor 11, comprising a radiation detector 11A and a filter 9, that is optically coupled on one side to detector 11a and to the waveguide 5 via a sidewall 5C thereof (which extends between the surfaces 5A and 5B), to detect 5 contact between the waveguide (and more particularly between the surface 5B of the waveguide through which the radiation is transmitted to the skin) and the skin. The terms "contact" and "optical contact," as used herein, refer not only to physical contact but also sufficient proximity between a surface of the waveguide and the skin that would result in detection of a signal by the sensor above a 10 predefined threshold.

In particular, the detector 11 detects a portion of the radiation that enters the waveguide through the surface 5B and exits the waveguide through the sidewall 5C. When the optical coupling between the surface 5B and the skin 15 surface is poor (e.g., when a substantial air gap is present between that surface and the skin) the amount of radiation that is leaked from sidewall 5C is low, and, thus, detector 11 detects a low signal. When the optical coupling between the surface 5B and the skin surface is good (e.g., when little or no gap exists between surface 5B and tissue 6 or when full contact is achieved between the tissue 6 and 20 the surface 5B) the amount of radiation that is leaked from sidewall 5C is substantially increased, and, thus, detector 11 detects a high signal.

The difference in the two signals is due to the total internal reflection of the light due to the difference in the indices of refraction of the waveguide and the 25 air. The waveguide has an index of refraction that is significantly greater than that of the air, approximately 1.45 to 1 respectively. Thus, in operation, the bulk of the radiation emitted from sources 2A and 2B will exit the waveguide via surface 5B, and only a small portion will be reflected internally, and only a small portion of that reflected radiation will exit sidewall 5C. When the surface 5B is 30 oriented toward the tissue 6, some of the emitted light will be reflected back to the device. The differences in the indexes of refraction, however, cause the light to refract upon reentry into waveguide 5 at angles that subsequently cause substantially all of the light to be totally internally reflected, such that essentially none of the light exits surface 5c.

When the device is touching the tissue, substantially more light reenters the waveguide 5 and passes through surface 5C. Thus, detector 11 then detects a significantly greater amount of light, thereby indicating that contact has been made (or that the device is positioned sufficient close to obtain a reading of MOD). The detector 11A of the sensor 11 indicates the presence of optical contact between the waveguide and the skin when its detection signal exceeds a pre-defined threshold, and it indicates the absence (or poor) optical contact between the waveguide and the skin when the detection signal is less than that threshold.

The principle is illustrated in FIGURES 1F and 1G. Figure 1F shows the condition where the waveguide 5 is not in contact with the tissue. Thus, the medium that the rays of light a, b and c travel through prior to entering the waveguide is air, which has an index of refraction of approximately one ( $n=1$ ), while the index of refraction of the waveguide is approximately 1.45. Thus, as shown in greater mathematical detail below, any ray traveling within the waveguide that strikes a waveguide/air boundary at an angle that is larger than 43.6 degrees (the critical angle, which is measured relative to a normal line extending from surface 5c) will be totally internally reflected. However, as illustrated in FIGURE 1F, all radiation that reenters the waveguide will be refracted to an angle that is larger than the critical angle relative to surface 5c. For example, ray a, which is normal to the air/waveguide boundary, travels in a straight line and parallel to surface 5c. Ray b strikes the air/waveguide boundary at an angle of incidence of 46.4 degrees from the normal relative to surface 5b, but is refracted to a steeper angle relative to surface 5c and is totally internally reflected. Similarly, ray c, which is nearly parallel to the air/waveguide boundary, is also refracted: to an angle slightly greater than the critical angle of 43.6 degrees relative to a line normal to surface 5c. Thus, ray c is also totally internally reflected.

In the case where the waveguide 5 is in contact with the tissue 6, as shown in FIGURE 1G, any light that strikes the tissue/waveguide boundary at an angle of incidence greater than z (46.4 degrees) will not be totally internally reflected at

the surface 5c. In this example, the indices of refraction of the tissue and the waveguide are approximately the same ( $n=1.45$ ). Therefore, the light will not refract significantly, and will continue to travel in an essentially straight line. Thus, any radiation having an angle of incidence greater than approximately angle 5 z will not be totally internally reflected. As shown in FIG. 1G, rays c and d are not totally internally reflected. Ray b, which has an angle of incidence on surface 5c at the critical angle y (43.6 degrees), is totally internally reflected. Any ray incident at a smaller angle than 43.6 degrees will not be totally internally reflected. Any ray incident at a larger angle than 43.6 degrees will be totally 10 internally reflected.

Of course, many other embodiments are possible, including, without limitation, embodiments where the reverse is true, *i.e.*, the light is totally internally reflected until contact is made, thus causing the level of light detected 15 to drop significantly when contact is made. Thus, contact may be signaled when the light level drops below a defined threshold. Additionally, although it is preferable to use a waveguide having an index of refraction that is matched or nearly matched to that of the tissue, it is not essential. Alternate embodiments can be designed having indices of refraction that are not matched. For embodiments 20 used on the surface of the skin, it is preferable, though not essential, to use a lotion to facilitate the transfer of radiation from sources 2A and 2B to the skin, and even more preferable to use a lotion with an index of refraction that is matched to or nearly matched to the refractive index of the skin. Other tissues 25 may not require a lotion, especially tissues such as those of the oral cavity that may already be coated with natural moisture that will facilitate the transfer of light or other radiation.

With reference to FIGURES 1B and 1C, the functionality of the optical sensor 11 can be further understood by considering the geometry of total internal 30 reflection in greater detail in two cases: the case in which the waveguide 5 is not in contact with the skin (FIGURE 1B showing that an air gap separates the surface 5B of the waveguide and the skin) and the case in which the waveguide is in full contact with the skin (FIGURE 1C). In the first case, a portion of the radiation from the sources that travels through the waveguide is specularly

reflected by the waveguide/air interface and another portion enters the air gap and passes therethrough to strike the skin. The radiation rays reflected and/or scattered by the skin back towards the waveguide pass through the air gap and strike the surface 5B of the waveguide. Some of the light will enter the  
5 waveguide, but does so at angles (again, due to refraction at the waveguide-air interface) that in most cases result in their total internal reflection at the sidewall 5C.

When surface 5b is in air, the angle of incidence ( $\phi$ ) of a ray A incident  
10 on the surface 5c can be equal or greater than the minimum angle at which total internal reflections occurs, as indicated by the following relation:

$$\phi \geq \arcsin(n_m/n_w) \quad \text{Eq. (1)}$$

wherein,

15  $n_m$  denotes the index of refraction of the medium (e.g., air) surrounding the waveguide, and.

$n_w$  denotes the index of refraction of the material forming the waveguide.

In contrast, when the surface 5B is in contact with the skin (FIGURE 1C),  
20 the back-scattered radiation rays entering the waveguide strike the sidewall at angles that allow a substantial number of those rays to leave the waveguide to reach the sensor.

In many embodiments, in order to optimize the performance of the sensor,  
25 the index of refraction of the material forming the waveguide is selected to be significantly different than the index of refraction of the air. Preferably, the material forming the waveguide exhibits an index of refraction close to that of the skin, approximately  $n=1.45$ . In the present embodiment, the waveguide is made of fused silica having an index of refraction of approximately 1.45. In other  
30 embodiments, different media may be used, for example, sapphire, which has an index of refraction of approximately 1.7.

Further, as shown schematically in FIGURE 1D, the detector 11 is preferably placed relative to the sidewall of the waveguide such that a central ray

A in a solid angle corresponding to the detector's field-of-view forms an angle  $\theta$  of approximately 30 degrees relative to the sidewall 5C. Other angles are possible, and will vary depending on the physical properties of the materials involved, including the material of the waveguide, the tissue involved (skin, oral tissue, and other tissues), and the material between the waveguide and the tissue (air, water, blood, etc.). Each will have a different index of refraction, and thus will result in different values for the optimal angle of the detector 11A. In some such embodiments, it may be preferable to include an additional prism on the surface (e.g., surface 5c in FIG. 1A), such as a right angle fused silica prism.)

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Referring again to FIGURE 1A, the device 1 further includes a feedback mechanism 12 in communication with the optical sensor 11, the detector 10, as well as the sources 2A and 2B. The feedback system 12 ignores the output signal from detector 10 when the optical sensor indicates no or poor optical contact between the waveguide (e.g., in this embodiment, between the surface 5B of the waveguide) and the skin. During operation, however, sources 2A and 2B will be on continuously or engaged at regular intervals to check for contact. (In some embodiments, the source or sources that provide the radiation to measure a physical characteristic of the skin may also provide additional radiation for other purposes, such as treatment or diagnosis. In such embodiments, the feedback system will control the source or sources to ensure that other radiation is provided at the proper time, depending on the detection of contact.)

More specifically, in this embodiment, the feedback system 12 includes a processor 12A that receives the output signals of the detector 11A of the sensor. The processor compares the detector's output signal with a pre-defined threshold to determine whether an appropriate optical contact exists between the waveguide's surface 5B and the skin (a detector signal that is less than the threshold indicates no optical contact between the waveguide and the skin). If the output signal of the sensor's detector is less than the threshold, the processor ignores the output of detector 10, or, alternatively, may inhibit operation of the device such that no measurement of a physical characteristic of the tissue or treatment of the tissue is provided. For example, in this embodiment, the processor 12A can send control signals to a switching unit 12B that, in turn,

ignores the output of detector 10. Sources 2A and 2B will always be engaged (either continuously or periodically) because they provide the radiation that is detected by the detector 11A to determine if the system is in contact with the tissue. (Alternatively, a separate light source could be provided that provides 5 radiation to be detected by detector 11A, and thereby allow sources 2A and 2B to be engaged only when measuring a physical characteristic of the tissue.)

As discussed in more detail below, the processor 12A also operates on the 10 output signals received from the detector 10 to determine a skin characteristic of interest. In other embodiments, the sensor 11 has its own dedicated processor that operates on the output signal of the sensor's detector 11A to determine whether or not the waveguide is in optical contact with the skin, and sends that information to the feedback system 12.

15 With continued reference to FIGURE 1A, as noted above, the processor 12A can also analyze the signals generated by the detector 10, in response to detection of the backscattered radiation from the skin illuminated by the radiation generated by the sources 2A and 2B, to determine a skin characteristic of interest, such as the concentration of melanin in the skin. The term "backscattered 20 radiation," as used herein refers to radiation that returns from the illuminated skin to the waveguide via reflection and/or scattering events.

By way of example, the device 1 can be employed in the following manner to determine the melanin concentration in a skin segment. For example, 25 the sources 2A and 2B can be sequentially activated to illuminate a skin segment that is contact with the waveguide after the optical sensor 11 detects optical contact between the waveguide's surface 5B and the skin. The sources can provide the radiation at wavelengths of 645 nm and 700 nm in different temporal intervals. A portion of the radiation illuminating the skin penetrates the skin and 30 passes through the epidermis to reach the dermis via passage through the dermis/epidermis junction (DE junction). As the skin is a turbid medium, the radiation entering the skin undergoes many scattering and/or reflection events, especially in the dermis layer. Some of the radiation is absorbed by melanin, particularly as it passes through the dermis/epidermis junction, at which the

melanin concentration is high in this example. The multiple scattering/reflection events cause some of the radiation to be coupled out of the skin back into the waveguide.

5 Due to the absorption characteristics of melanin, a relatively high level of light will be backscattered to waveguide 5, if the skin contains a relatively low amount of melanin. Conversely, a relatively low level of light will be backscattered to waveguide 5 if the skin contains a relatively high amount of melanin. As a result of the interaction of the radiation entering the skin with  
10 melanin, the radiation that is backscattered into the waveguide, therefore, carries information regarding the MOD.

By way of example and without being limited to any particular theory, the intensity of the radiation backscattered from the skin into the waveguide at each  
15 of the two illumination wavelengths utilized in this embodiment can be characterized by the following relation:

$$R_d^\lambda = \kappa(T_\lambda^2 R_{dermis}) \quad \text{Eq. (2)}$$

20 wherein,

$R_d^\lambda$  denotes diffuse reflectance (backscattered radiation intensity) from the skin region illuminated with radiation at wavelength  $\lambda$ ,

25  $\kappa$  is a proportionality constant that can depend, e.g., on the intensity of the illuminating radiation as well as geometrical factors associated with coupling of the radiation into the skin,

$T_\lambda$  is the transmission coefficient through the skin at the illumination wavelength  $\lambda$ , which depends on the melanin concentration, and

$R_{dermis}$  denotes diffuse reflectance from the dermis.

The transmission coefficient  $T_\lambda$  depends on the concentration of melanin in the  
30 illuminated skin region, as melanin can absorb some of the radiation. Hence,  $R_d^\lambda$  carries information regarding melanin concentration. In this exemplary embodiment, the radiation wavelengths are selected to be in a range of about 600 nm to about 900 nm to ensure that the interaction of the radiation with blood is

minimal. As such, the above Eq. (2) does not take into account the contributions of blood.

5      The apparent optical density ( $OD_\lambda$ ) of the illuminated skin at an illumination wavelength ( $\lambda$ ) can be determined from the following relation:

$$OD_\lambda = -\log R_d^\lambda \quad \text{Eq. (3)}$$

As the above transmission coefficient  $T_\lambda$  is proportional to melanin optical density at wavelength  $\lambda$  (referred to as  $OD_\lambda^{mel}$ ), Eq. (3) can be rewritten in the following manner:

$$OD_\lambda = OD_\lambda^{mel} - \log R_{dermis} \quad \text{Eq. (4)}$$

15     The selection of the radiation wavelengths in a range of about 600 nm to about 900 nm ensures that while  $T_\lambda$  is wavelength dependent,  $R_{dermis}$  is substantially independent of the illumination wavelength. As such, the difference between apparent optical density ( $OD_\lambda$ ) at two wavelengths, and more generally the slope of apparent optical density in the spectral range of about 600 nm to about 900 nm, 20    is proportional to the melanin concentration. For example, a melanin index ( $M$ ) can be defined in the following manner:

$$M = 100(OD_{\lambda_1} - OD_{\lambda_2}) \quad \text{Eq. (5)}$$

25     By way of example, in many embodiments, the processor 12A employs the above mathematical relations to calculate the melanin optical density based on the detected intensity of the radiation diffusely reflected (backscattered) from the skin.

30     By way of illustration and only for the purpose of showing the efficacy of the systems and methods of the invention for measuring the skin melanin optical density, a prototype device was constructed according to the teachings of the

invention. A comparison of melanin measurements performed by that device on a number of subjects with corresponding measurements performed by a few conventional devices on the same subjects showed that the prototype device provides enhanced performance, particularly significantly better measurement 5 repeatability. The radiation spectrum of the two LEDs utilized in the prototype device is shown in FIGURE 2. While one LED exhibits a maximum radiation intensity at a wavelength of about 645 nm, the other LED has a maximum radiation intensity at a wavelength of about 700 nm. FIGURE 3 provides raw signal generated by the detector measuring backscattered radiation for 10 determining melanin concentration (referred to in the figure as "pigmentometer signal") in response to triggering of the LEDs in different time intervals. The raw data can be analyzed, e.g., in a manner discussed above, to arrive at the melanin index.

15 By way of further illustration, in another device similar to the prototype discussed above in which the wavelengths used were 660 and 910 nm respectively, FIGURE 4 shows the sensitivity of the device as a function of its tilt relative to the skin (rocking sensitivity) and FIGURE 5 shows the sensitivity of the device as a function of the thickness of air gap between the device and the 20 skin. It should be understood that the data is presented only for illustration purposes, and is not intended to necessarily indicate the optical signal intensities that can be obtained by a device of the invention. Many other embodiments are possible, and the data provided is specific to the prototype devices that were tested, which were similar in design to the embodiment described in conjunction 25 with device 1.

Although in the above embodiment, two sources, each of which generates radiation at a different wavelength, are employed, in some other embodiments, a single source generating radiation at two or more different wavelengths can be 30 employed. To measure MOD, the sources preferably emit radiation in a range of about 600 nm to about 900 nm. By way of example, as shown schematically in FIGURE 6, a dermatological device 13 includes a single radiation source 14 capable of generating radiation at two or more wavelengths, e.g., a bicolor light emitting diode (bicolor LED), that is capable of generating radiation at two or

more wavelengths in a range of about 600 nm and about 900 nm. Again, the wavelengths 645 and 700 are thought to be preferable, but many other combinations of wavelengths are possible.

5       Device 13 further includes a control unit 15 having a processor 15a can actuate the bicolor LED 15 so as to generate the color of interest. For example, the control unit can cause the LED to generate the various wavelengths in different temporal intervals for illuminating a skin region of interest. More specifically, similar to the previous embodiment, the radiation generated by the  
10      LED 15 is optically coupled to a waveguide 5 via passage through a polarizer 3. The waveguide 5 transmits the radiation to tissue 6, in this case human skin. A detector 10 that is optically coupled to waveguide 5 via a filter 8 and polarizer 7, receives at least a portion of the radiation that is diffusely back-reflected (backscattered) from the illuminated skin. Similar to the previous embodiment,  
15      the detector 10 is coupled to the polarizer 7 having a polarization axis orthogonal to that of the polarizer 3 to suppress, and preferably eliminate, the detection of specularly reflected radiation, especially specular reflections at the surface of the illuminated skin, by the detector 10. Further, the filter 8 prevents ambient radiation noise, e.g., due to artificial ambient lighting units, from reaching the  
20      detector 10.

The processor 15a receives the output signals generated by the detector 10, in response to illumination of the skin at two or more wavelengths, and analyzes those signals, e.g., in the manner discussed above, to determine a physical  
25      characteristic of the skin such as the MOD. Further, similar to the previous embodiment, the device 13 includes an optical sensor 11 having a detector 11a optically coupled to a filter 9, which can determine whether the waveguide is in contact with the skin, also in a manner similar to the detector 11 as described in conjunction with FIGURE 1A.

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The embodiments of a device according to the teachings of the invention are not limited to those discussed above. For example, FIGURE 7A schematically depicts a dermatological device 16 according to another embodiment of the invention that includes a radiation source 17 whose radiation

is coupled via a prism 18 to a waveguide 19. Similar to the previous embodiments, a polarizer 3 is coupled to the source 17 and polarizes the source radiation. (Though many materials are possible, the prism in this embodiment is made of CaF<sub>2</sub>.) The waveguide 19 includes a reflective sidewall 19a that reflects the radiation entering the waveguide to a waveguide surface 19B that is adapted for contact with the skin. The waveguide 19 can be, for example, a block formed of a material, such as fused silica, having an index of refraction that is preferably close to that of the skin, and reflective sidewall can be formed, e.g., by coating a reflective material (such as silver) on a waveguide surface. In this embodiment, the source 17 and the prism 18 are positioned relative to the waveguide such that the radiation rays entering the waveguide are reflected by the sidewall 19a to tissue 6. The reflected radiation strikes the skin/waveguide interface at surface 19B at an angle of incidence (AOI) that, in the absence of optical contact between the surface 19B and the skin, results in total internal reflection (TIR) of those rays, thus preventing them from leaving the waveguide, as shown schematically in FIGURE 7B. For example, the angles of incidence of the rays striking the surface can be greater than the minimum angle required for causing TIR at the waveguide/air interface (See above Eq. 1) to ensure total internal reflection of those rays.

20

In contrast, when the waveguide's surface 19B is in optical contact with the skin (FIGURE 7A), the rays reflected by the sidewall 19a pass through the surface 19B to enter the skin. (The waveguide/skin interface does not cause total internal reflection of those rays). The use of TIR provides an additional safety mechanism that prevents inadvertent exposure to the radiation coupled to the waveguide (e.g., exposure of a user's eye) by ensuring that radiation is emitted through the waveguide to the external environment only when the waveguide is in contact with the skin. It also increases the sensitivity of the contact sensor, because it utilizes the principle of TIR twice.

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The device 16 also includes a detector 10 that is optically coupled to waveguide 19 via a filter 8 and polarizer 7. Detector 10 detects radiation that is diffusely back-reflected (backscattered) from the skin. The device 16 also includes an optical sensor 11 having a detector 11a optically coupled to a filter 9,

which can determine whether the waveguide is in contact with the skin, also in a manner similar to the detector 11 as described in conjunction with FIGURE 1A. However, as described in conjunction with FIGURE 1A, the operation of the device is reversed. In other words, where device 1 as shown in FIGURE 1A  
5 senses contact when it receives a level of light that exceeds a particular threshold, device 16 senses contact when it receives a level of light that is below a particular threshold. Like the previously described embodiments, detector 11a is optically coupled to waveguide 19 via a filter 9. Unlike the previous embodiments, the detector 11a is also optically coupled to waveguide 19 via a polarizer 4 located  
10 between filter 9 and waveguide 19. Polarizer 4 has a polarization axis that is orthogonal to that associated with the source polarizer 3. Thus, device 16 suppresses the detection of specular reflections at both detectors 10 and 11a. Further, the filters 8 and 9 block ambient radiation from reaching the detectors.

15 FIGURE 8A schematically depicts a device 20 in accordance with another embodiment of the invention that also relies on reflection of light from reflective sidewalls of a waveguide to couple light into the skin and to inhibit its coupling when there is no contact between the waveguide and the skin. Rather than utilizing a single radiation source, the device 20 includes two radiation sources 22  
20 and 24, each of which generates radiation at a different wavelength (e.g., in a range of 600 nm to 900 nm). The radiation sources 22 and 24 are optically coupled to a waveguide 26 via a prism 18. The waveguide 26 includes two reflective sidewalls 26a and 26b, each of which directs the light received from one of the radiation sources to a surface 26c of the waveguide such that the radiation  
25 is internally reflected by that surface in absence of contact between the waveguide and the skin, and is transmitted through that surface to the skin when there is contact. The reflective sidewalls can be formed, e.g., by depositing a reflective material (e.g., silver) on the surfaces of waveguide 18. The waveguide can be formed of a material that is transmissive to the radiation generated by the sources  
30 22 and 24, and, in the present embodiment, is fused silica. Similar to the previous embodiments, the radiation that is backscattered from the skin can be detected by a detector (not shown) whose output signals are analyzed by a processor (not shown) to determine a skin characteristic. Further, the sensor 11 is optically coupled to an opening 26D in the sidewall 26b, which is created by an absence of

reflective coating at the opening. The opening allows light to leak from waveguide 26 and be detected by sensor 11.

Device 20 also includes polarizers 78 and 79 and prism 80. Light sources 5 22 and 24 are optically coupled to waveguide 26 via the polarizers 78 and 79 and the prism 80. Polarizer 78 has a polarization axes that is orthogonal to that associated with polarizer 79, which, as discussed above, serves to eliminate surface and other reflections not associated with the parameter being measured. Additionally, sensor 11 further includes a detector 11a and a filter 9, located 10 between detector 11a and opening 26D. The filter serves to reduce the amount of ambient radiation that reaches the detector 11a.

FIGURE 8B schematically depicts a device 100 according to another embodiment that utilizes two radiation sources 102 and 104 for illuminating the skin by coupling the radiation via a prism 106 to a waveguide 108 having two reflective sidewalls 108a and 108b, each of which is adapted for directing primarily radiation from one of those sources to the skin. The device 100 further includes two detectors 110a and 110b for detecting radiation backscattered from the skin. As in previous embodiments, the detected backscattered radiation can be 20 analyzed by a processor (not shown) to determine a skin characteristic of interest (e.g., MOD). Similar to some of the previous embodiments, the radiation sources 102 and 104 are coupled to polarizers 112a and 112b, respectively, while the detectors 110a and 110b are coupled, respectively, to orthogonal polarizers 114a and 114b for suppressing the detection of specular reflections. Further, the 25 detectors 110a and 110b are coupled to filters 116a and 116b, which filter out ambient radiation noise.

FIGURE 9 schematically depicts a dermatological device 27 according to another embodiment of the invention that relies on the detection of radiation transmitted through tissue 6 (in this case skin) to determine a characteristic of the tissue (in this case MOD). The exemplary device 27 includes a radiation source 30 14, e.g., one capable of generating radiation of at least two wavelengths in a range of about 600 nm to about 900 nm, that is optically coupled to a prism 28. The prism 28 receives the radiation from the source through a surface 28a thereof and

couples that radiation to the skin via another surface 28b, which is adapted for optical contact with the skin. The index of refraction of the material forming the prism can be selected so as to adjust the range of angles at which the radiation traveling through the prism enter the skin via refraction at the prism/skin  
5 interface. The process is similar to that described above in conjunction with device 1.

The device 27 further includes a detector 10, which is coupled to a filter 8, which filters out ambient radiation. The detector 10 is positioned at a  
10 predetermined distance from the prism to detect at least a portion of the radiation coupled by the prism 28 into the skin and transmitted through a skin portion separating the prism 28 from the detector 10. The precise angle of prism 28 and the distance between prism 28 and detector 10 can be selected to optimize a particular design, and several angles and distances could be used, some being  
15 more optimal than others. In the present embodiment, the angle at which radiation is directed to the tissue 6 is approximately 45 degrees, and the distance between prism 28 and detector 10 is approximately 1 cm. In the above device 27, the distance between the source and the detector can be adjusted to tune the device for measuring the concentration of a given chromophore (pigment) of  
20 interest at different skin depths, for example, by selecting wavelengths that are better absorbed by deeper tissues or over longer distances, by adjusting the distance between the prism 28 and the detector 10, and/or by utilizing additional wavelengths and/or detectors to differentiate the relative amounts of the chromophore at different positions or depths in the tissue 6.

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The light entering the skin is transmitted diffusely (via multiple scattering and/or reflections events) to the detector. The transmitted light can also carry information regarding the concentration of a chromophore of interest, as a result of its interaction with that chromophore (e.g., via absorption of some of the light  
30 by the chromophore). A processor 29 in electrical communication with the detector 10 and light source 14 analyzes the detector's output signals generated in response to illumination of the skin at two or more radiation wavelengths (e.g., two wavelengths in a range of about 600 nm to about 900 nm) to determine a characteristic of the skin, such as melanin optical density.

The device 27 provides a high sensitivity in measuring the concentration of a pigment of interest, as it relies on diffuse transmission of photons over a long distance through the skin. This allows the device to be employed in a variety of 5 applications. By way of example, as shown schematically in FIGURE 10, the device 27 can be employed to detect an iris 30 within the eye. For example, as the device 27 is scanned over the skin, it can detect significant absorption of the radiation transmitted through the illuminated skin (especially at wavelengths in a range of about 600 to about 800 nm) by the iris 30, thereby detecting its presence. 10 Such detection of the iris can be useful, for example, in devices that must avoid damaging an eye when providing laser or other radiation treatment to the skin. The device 27 can be incorporated in such treatment devices to provide a signal when the treatment device is over the eye, and preferably inhibit activation of (or deactivate) the treatment laser source based on such eye detection signal.

15

In other embodiments, the dermatological devices of the invention can employ optical fibers for coupling radiation from a source into the skin and/or decoupling radiation backscattered by or transmitted through an illuminated skin segment. By way of example, FIGURE 11A schematically depicts a 20 dermatological device 32 according to such an embodiment of the invention that includes a source 12 optically coupled to a plurality of optical fibers 33, each of which receives the radiation generated by the source at one end thereof and, during operation, can be optically coupled at another end to a tissue 6 (in this case, skin). In many embodiments, the source 12 is capable of generating 25 radiation at two or more wavelengths, e.g., two or more wavelengths in a range of about 600 nm to about 900 nm. The device 32 further includes another set of optical fibers 34, each of which is optically coupled at one end thereof to the skin at a location separated by a selected distance from the location at which the radiation enters the skin via the fibers 33a. In this manner, the optical fibers 34 30 collect at least a portion of the radiation that is diffusely transmitted (radiation transmitted via multiple scattering and/or reflection events) through a skin portion disposed between the ends 33a of the fibers 33 and the ends 34a of the fibers 34, and is coupled into the fiber 34, e.g., via scattering/reflection events. Each of the optical fibers 34 is optically coupled at another end, via the a filter 8 that filters

out ambient radiation noise, to a detector 10 that receives the radiation collected by the optical fibers 34.

A processor 36 processes the output signals of the detector 10 to determine  
5 a characteristic of the illuminated skin segment. For example, in cases where a measurement of the melanin optical density of the skin is desired, the source 14 can be selected to provide at least two radiation wavelengths in a range of about 600 nm to about 900 nm. The source can be activated to illuminate the skin 6 via the fibers 33 at these two wavelengths in different temporal intervals. And the  
10 output detection signals generated by the detector 10 corresponding to the two illumination wavelengths can be analyzed by the processor 36 to determine the melanin concentration by utilizing, e.g., the mathematical equations discussed above.

15 In another embodiment schematically shown in FIGURE 11B, a dermatological device 37 in accord with the teachings of the invention includes a plurality of optical fibers 38 for transmitting the radiation generated by a source 14 to tissue 6. Waveguides 39 guide the radiation from tissue 6 to a detector 10. Waveguides 39 have a substantially cylindrical hollow structure, as shown in  
20 FIGURE 11C. Waveguides 39 collect at least a portion of the radiation transmitted through the skin from the illumination site to the waveguide. A detector 10 is optically coupled to the waveguide, via a filter 8, to receive the radiation collected by the waveguide. Similar to the previous embodiment, a processor 36 operates on the output signals generated by detector to determine a  
25 desired characteristic of the skin.

As shown in FIGURE 11D, in some embodiments, the cylindrical waveguide is formed by disposing a plurality of optical fibers 39a within an annular housing 39b, e.g., a flexible enclosure. In some alternative embodiments,  
30 the waveguide can be an annulus formed of a suitable material, such as fused silica. By way of further illustration, FIGURE 11E schematically depicts a top view of an area 40 under observation (the sensing area) by the device 37. The perimeter of the sensing area is defined by a proximal end of the cylindrical waveguide 39 shown in FIGURES 11C and 11D. The radiation energy is coupled

into the area 40 via a proximal end of optical fibers 38 (the area 38b illustrates the top view of the skin area illuminated by the fibers 38). In this embodiment, the waveguide can be selected such that sensing area is large so as to reduce measurement sensitivity to local irregularities. However, other embodiments can 5 be sized to provide relatively larger sensing areas or relatively smaller sensing areas. Additionally, alternate embodiments can include other configurations such as an internal waveguide located inside waveguide 39 that replaces fibers 38. Similarly, light can be provided to the sensing area through a hollow space within the waveguide 39 without using fibers 38 or another waveguide.

10

By way of another example, FIGURE 12 schematically depicts a dermatological device 42 that includes an optical fiber 43. Optical fiber 43 comprises a core 43a surrounded by a cladding 43b. Optical fiber 43 is optically coupled at a proximal end thereof to a radiation source 44 to receive radiation 15 from the source after its passage through a beam splitter 45, and is coupled at its distal end to a skin region 6 to transmit the received radiation to the skin. The radiation that is backscattered into the fiber from the illuminated skin region travels back through the fiber along the same path and exits from the proximal end towards the beam splitter 45, which in turn directs the backscattered radiation 20 to a detector 46, which is coupled to a filter 47. A processor 48 determines one or more characteristics of the skin based on the output signals generated by the detector. By way of example, in some embodiments, the radiation source 44 provides two or more radiation wavelengths, e.g., two or more wavelengths in a range of about 600 nm to about 900 nm, and the processor analyzes the output 25 signals of the detector 46 corresponding to backscattered radiation at these wavelengths to determine a skin characteristic (e.g., melanin concentration), e.g., in a manner discussed above.

In this embodiment, the device 42 further includes an optical sensor 49, 30 having a detector 49a coupled to a filter 49b, that is optically coupled to the fiber 43 at a fiber section A from which the cladding is removed. The removal of the cladding allows a portion of the backscattered radiation to leak from the core into the sensor's detector. The detection signal generated by the sensor's detector can then be utilized to determine whether the fiber's distal end is in contact with the

skin. For example, the detection of radiation intensity below a selected threshold by the sensor can indicate lack of contact between the fiber's distal end and the skin while the detection of radiation above that threshold can indicate contact.

5 FIGURE 13 schematically depicts a dermatological device 50 in accordance with another embodiment of the invention that also employs an optical fiber 51 for coupling radiation into the skin and collecting radiation backscattered from the illuminated skin. More specifically, optical fiber 51 has a split end 52 that provides an input port 52a optically coupled to a radiation source 10 53 for receiving radiation from the source, and an output port 52b for coupling radiation backscattered into the fiber to a detector 54, via a filter 55. Similar to some of the previous embodiments, the source can provide two or more wavelengths of interest and the output of the detector 54 corresponding to the backscattered radiation at those wavelengths can be analyzed by a processor (not 15 shown) to determine a skin characteristic (e.g., the skin's melanin index).

Although the majority of the embodiments described herein are used for the measurement of MOD of skin by applying radiation at the surface of the skin, other embodiments are possible, both for measuring other characteristics and 20 other tissues. For example, given the potentially small size of the embodiments described in conjunction with FIGURES 11A-13, alternate embodiments of devices employing these concepts could be used to measure physical properties of internal tissues, for example, via an endoscope and/or incision.

25 A diagnostic dermatological device according to the teachings of the invention, such as those discussed above, can be coupled to a dermatological treatment device to provide information regarding one or more characteristics of the skin to be treated. For example, as shown schematically in FIGURE 14, a dermatological device 56 can include a treatment module 57 and a diagnostic 30 module 58 that is in communication with the treatment module. By way of example, the treatment module can include a radiation source 59 that provides treatment radiation. The treatment radiation can be coupled via one or more optics (not shown) through a radiation transmissive window 60 (such as a sapphire window) to the skin. Alternatively, the treatment module can receive the

treatment radiation from an external source, e.g., via an optical fiber. By way of example, U.S. Patent Appl. No. 10/154,756 entitled “*Cooling System for a Photocosmetic Device*,” which is herein incorporated by reference, provides teachings regarding dermatological treatment devices that can be employed in

5 constructing the treatment module 57. In this embodiment, the treatment module includes a feedback mechanism 62 that is in communication with the treatment source 59 and the diagnostic module 58. The feedback mechanism 62 can receive signals from the diagnostic module indicative of one or more skin characteristics, e.g., the melanin optical density.

10

In this exemplary embodiment, the feedback mechanism 62 applies control signals to the radiation source in response to the information regarding the skin characteristic received from the diagnostic module to adjust one or more parameters of the treatment radiation generated by the source, e.g., the power of 15 treatment radiation, the wavelength of the treatment radiation, pulse width and/or pulse repetition rate when pulsed radiation is used, or any other parameter of interest. In some cases, the diagnostic module can be utilized to allow activation of the treatment source only for treating certain skin types. For example, the treatment radiation source can be activated to treat only those persons whose skin 20 pigment levels (e.g., MOD) would result in the diagnostic wavelength signal, the ratio of the diagnostic signals at different wavelengths, as well as the background signals falling within predefined ranges (e.g., above or below certain thresholds.) By way of example, such parameters can be set such that most materials other than the skin would provide diagnostic signals outside a range that would be acceptable for 25 activating the treatment source. For example, when the skin characteristic corresponds to the MOD, the feedback module can control the treatment source to adjust its output power, e.g., to reduce the power when the measured melanin optical density is high and to increase it when that optical density is low. Further, in some cases in which the skin melanin concentration is above a predefined 30 threshold, the feedback mechanism can inhibit activation of the treatment source. This can be utilized, e.g., as a safety measure to ensure that the treatment radiation is applied only when appropriate (e.g., only to the skin having pigment levels within a predefined range).

In some embodiments, such adjustment of one or more parameters of the treatment radiation in response to the information provided by the diagnostic module can be accomplished in real-time. For example, as the device 56 is moved over the skin, the treatment module 57 lags behind the diagnostic module 58 such that the diagnostic module determines a desired characteristic of a skin segment to be treated prior to application of the treatment radiation to that segment by the treatment module. In this manner, the treatment module can utilize the information provided by the diagnostic module to adjust the treatment parameters (e.g., the power level of the treatment radiation) in real-time. For example, different portions of a skin patch under treatment can exhibit different pigment levels (e.g., different melanin concentrations). In such a case, the treatment module can adjust the power level of the treatment radiation as the treatment radiation is applied to those skin portions.

15       In embodiments in which the treatment source is external to the treatment module, the adjustment of one or more parameters of the treatment radiation in response to information provided by the diagnostic module can be achieved, e.g., by applying control signals to the source and/or to one or more elements disposed in the treatment module and in optical coupling with the source. For example, a 20 shutter disposed within the treatment module can be controlled to allow or inhibit application of the treatment radiation to the skin based on one or more skin characteristics determined by the diagnostic module. Further, one or more neutral density filters can be utilized to modulate the power level of the treatment radiation.

25       With continued reference to FIGURE 14, the exemplary device 56 further includes a speed sensor 64 that measures the device's scanning speed as it scans the skin. The speed sensor can be configured to allow a directional scan (uni-directional in this case, although other embodiments are possible, including bi-directional and multi-directional) such that the diagnostic module 58 would lead the treatment module. Examples of speed sensors suitable for use in the device 56 can be found in U.S. Patent Application No. 11/098,015, filed April 1, 2005 entitled "*Methods and products for producing lattices of EMR-treated islets in tissues, and uses therefore,*" which is herein incorporated by

reference. In some embodiments, the feedback mechanism can be incorporated within the speed sensor.

In some embodiments, the treatment and the diagnostic modules, and in  
5 some cases the speed sensor as well, can be integrated within a single enclosure  
so as to provide a compact device. Further, in many such embodiments, the  
diagnostic and the treatment sources can share a common optical path so that a  
tissue region can be treated in real-time as its one or more characteristics (such as  
melanin optical density) are measured. Such a device can be particularly useful  
10 when the treatment is applied in a stamping mode.

By way of example, FIGURE 15 schematically depicts a dermatological device 65 having an enclosure 66 in which a treatment radiation source 67 for generating treatment radiation and a radiation source 68, e.g., a source generating  
15 two or more wavelengths are disposed. The radiation from the treatment source is coupled via a lens 69, after passage through a beam splitter 70, into a waveguide 71, e.g., a sapphire block. The radiation from the source 68 passes through a beam splitter 72 to be reflected by the beam splitter 70 into the waveguide. The waveguide 71 guides both the treatment and the radiation into a skin region in contact therewith. A portion of the radiation that is backscattered from the illuminated skin region is reflected by the beam splitters 72 and 70 into a detector 73 via a filter 74. Detector 73 generates output signals that can be analyzed by a processor 75, e.g., in a manner discussed in connection with the previous  
20 embodiments, to determine a characteristic of the tissue 6 (e.g., the melanin concentration of skin). The device 65 can further include an optical sensor 76, such as those discussed above, that is optically coupled to a sidewall of the waveguide 71 for determining contact between the waveguide and the skin. The processor can operate on the output signals generated by the sensor to control the treatment radiation source (e.g., inhibit its activation and/or deactivate it when  
25 there is no contact between the waveguide and the skin). In addition, the processor can further adjust one or more parameters of the treatment radiation (e.g., power level, pulse width, or repetition rate) in response to the output signals of the optical sensor 76. Similar to certain embodiments discussed above, a plurality of polarizers and filters can be employed to suppress detection of  
30

radiation specularly reflected at various interfaces and/or ambient radiation. Further, in some embodiments, the device 65 can include a speed sensor 77 that can measure the speed of the device 65 as it is scanned over the skin, and in some cases apply control signals to the treatment source (e.g., modulate the source's 5 power in response to the scan speed).

In other embodiments, more than two wavelengths can be used to detect a physical property of the skin. For example, by using three wavelengths, the apparent age of the skin can be determined. The backscattered radiation from a 10 skin region can be measured using three or more wavelengths. Although many wavelengths are possible, the wavelengths chosen are preferably in a range of about 600 nm to about 900 nm, such as 645, 700 and 900 nm. As in the case of measuring MOD, selection of wavelengths in this range takes advantage of the absorption characteristics of skin in that wavelength range. The age of the skin 15 can correspond to its chronological age or its apparent age. For example, in some cases, the skin of a young individual (e.g., a person in her twenties) may nonetheless exhibit a much older apparent age, e.g., due to excessive sun exposure and/or smoking. The devices discussed above can be employed to practice this aspect of the invention, e.g., by selecting an appropriate radiation source (or 20 sources) that provide the requisite radiation wavelengths. Reflectance values at these three wavelengths can be analyzed to determine MOD and skin diffusion properties, and the skin age can be correlated to the skin diffusion properties.

Similarly, by using three or more wavelengths, the error in measurement 25 can be reduced. For example, two wavelengths can be selected that are close in value (e.g., approximately 10 nm apart) while the third wavelength is further spaced, e.g., 640, 650 and 700 nm. The use of the additional wavelength will help reduce errors due to inconsistencies in measurements caused by other physical characteristics of the tissue.

30

In some embodiments, the wavelength of the radiation generated by a radiation source utilized for providing radiation can depend to some degree on the temperature of that source. In such embodiments, wavelength versus temperature data for the radiation source(s) can be stored, e.g., on a memory module, to be

utilized by the processor to calibrate the radiation wavelength (to calculate the actual wavelength from the nominal wavelength).

Although the above embodiments generally described utilizing  
5 wavelengths in a range of about 600 nm to about 900 nm to measure, e.g., the MOD of skin, the various embodiments discussed above can be generally employed with radiation source generating radiation with wavelengths in other ranges including a range of about 300 nm to about 1200 nm to measure the concentration of other chromophores (such as hemoglobin). For example, two forms of  
10 hemoglobin have primary absorption bands in a spectral range of 405 nm to 430 nm (the Soret band) and secondary bands in a range of 540 nm to 580 nm. In some embodiments, the concentration of the hemoglobin can be measured by detecting the backscattered radiation at two or more wavelengths in those bands. Even broader or different wavelength ranges can be used for other purposes or to  
15 use other types of radiation sources.

Those having ordinary skill in the art will appreciate that various modifications can be made to the above embodiments without departing from the scope of the invention.

20

What is claimed is:

**CLAIMS:**

1. A dermatological device for determining a physical characteristic of a portion of tissue, comprising:

5

a radiation source assembly configured to generate radiation having at least a first wavelength;

10 a waveguide coupled to said source assembly for directing the radiation from the source to said portion of said tissue, and having a surface configured to irradiate said portion with said radiation;

15 a detector coupled to said waveguide and configured to detect radiation from said source, said detector generating signals indicative of the level of radiation detected; and

a processor in communication with said detector to process said signals and calculate a physical characteristic of the skin region;

20 wherein said detector is configured to detect said radiation from said source after said portion of said tissue has been irradiated with said radiation from said source.

25 2. The device of claim 1, wherein said radiation source assembly includes two or more radiation sources.

30 3. The device of claim 2, wherein a first radiation source produces radiation having said first wavelength and wherein a second radiation source produces radiation having a second wavelength.

4. The device of claim 1, wherein said radiation source assembly includes a single radiation source.

5. The device of claim 4, wherein said first radiation source produces radiation having said first wavelength and further produces radiation having a second wavelength.

5 6. The device of claim 1, wherein said radiation source assembly includes at least one of a light emitting diode (LED), a bi-color LED, a tunable radiation source, and a laser radiation source.

7. The device of claim 1, wherein said radiation source assembly is 10 configured to generate radiation having a second wavelength.

8. The device of claim 7 wherein said first and second wavelengths are selected from a range of about 350 nm to about 1200 nm.

15 9. The device of claim 7 wherein said first and second wavelengths are selected from a range of about 600 nm to about 900 nm.

10. The device of claim 1 wherein said first wavelength is selected from a range of about 350 nm to about 1200 nm.

20 11. The device of claim 1 wherein said first wavelength is selected from a range of about 600 nm to about 900 nm.

12. The device of claim 1, further comprising a contact sensor indicating 25 whether said surface of the optical waveguide is in contact with the skin.

13. The device of claim 12, wherein said contact sensor is configured to detect a level of said radiation of said first wavelength.

30 14. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is not in contact with said tissue when said contact sensor detects that said level is below a threshold.

15. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is in contact with said tissue when said contact sensor detects that said level is above a threshold.

5

16. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is not in contact with said tissue when said contact sensor detects that said level is above a threshold.

10

17. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is in contact with said tissue when said contact sensor detects that said level is below a threshold.

15

18. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to totally internally reflect said radiation along said boundary when said surface is not in contact with said tissue.

20

19. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to not totally internally reflect said radiation along said boundary when said surface is in contact with said tissue.

25

20. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to totally internally reflect said radiation along said boundary when said surface is in contact with said tissue.

30

21. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to not totally internally reflect said radiation along said boundary when said surface is not in contact with said tissue.

22. The device of claim 12, wherein said radiation source assembly is configured to generate radiation having a second wavelength, and said contact sensor is configured to detect a level of said radiation of said first wavelength and of said second wavelength.

5

23. The device of claim 12, further comprising:

10 a first polarizer configured to filter radiation of a first polarity from said radiation source assembly; and

a second polarizer configured to filter radiation of a second polarity entering said contact sensor.

15 24. The device of claim 12, further comprising a filter disposed between the contact sensor and the waveguide.

20 25. The device of claim 1, wherein said radiation source assembly is configured to generate radiation having three or more wavelengths.

25 26. The device of claim 1, wherein said skin characteristic is selected from the group consisting of melanin index, collagen content, diffusion, and erythema measurement.

30 27. The device of claim 1 wherein said waveguide is formed of a material having an index of refraction in a range of about 1.4 to about 2.5.

28. The device of claim 1, further comprising:

30 a first polarizer configured to filter radiation of a first polarity from said radiation source assembly; and

a second polarizer configured to filter radiation of a second polarity entering said detector.

29. The device of claim 1, further comprising a filter disposed between said waveguide and said detector.

5

30. The device of claim 1, further comprising a controller coupled to said radiation source assembly, said controller configured to activate said radiation source assembly to produce radiation of different wavelengths at different times.

10

31. The device of claim 1, wherein said waveguide is an optical fiber.

32. The device of claim 1, further comprising at least one additional waveguide coupled to said source assembly.

15

33. The device of claim 32, wherein said at least one additional waveguide is an optical fiber.

20

34. A dermatological device for determining a physical characteristic of a portion of tissue, comprising

a radiation source assembly configured to generate radiation having first and second wavelengths;

25

a waveguide coupled to said source assembly for directing the radiation from the source to said portion of said tissue, and having a surface configured to irradiate said portion with said radiation;

30

a detector coupled to said waveguide and configured to detect radiation from said source, said detector generating signals indicative of the level of radiation detected;

a processor in communication with said detector to process said signals and calculate a physical characteristic of the skin region; and

a contact sensor optically coupled to said waveguide along a boundary and configured to detect a level of said radiation;

5       wherein said detector is configured to detect said radiation from said source after said portion of said tissue has been irradiated with said radiation from said source.

35.     The device of claim 34, wherein said first and second wavelengths are  
10     in a range of about 300 nm to about 1200 nm.

36.     The device of claim 34, wherein said first and second wavelengths are  
in a range of about 600 nm to about 900 nm.

15     37.     The device of claim 34, wherein said first and second wavelengths are  
in a range of about 630 nm to about 730 nm.

38.     The device of claim 34, wherein said first wavelength is approximately  
645 nm.

20     39.     The device of claim 34, wherein said first wavelength is approximately  
700 nm.

40.     The device of claim 34, wherein said first wavelength is approximately  
25     645 nm and said second wavelength is approximately 700 nm.

41.     The device of claim 34, wherein said waveguide surface adapted for  
contact with the tissue inhibits transmission of radiation in absence of skin  
contact by total internal reflection of radiation reflected by the sidewall  
30     thereto.

42.     The device of claim 34, further comprising a feedback mechanism in  
communication with said sensor and said source, wherein said feedback  
mechanism is capable of inhibiting activation of the source when the sensor

indicates lack of optical contact between the waveguide and the source, and capable of activating the source when the sensor indicates optical contact.

43. The device of claim 34, further comprising a processor in  
5 communication with the detector, said processor determining a skin characteristic based on said detector output.

44. The device of claim 34, wherein said waveguide is an optical fiber.

10 45. The device of claim 34, further comprising at least one additional waveguide.

46. A dermatological device, comprising  
15 at least one radiation source,

a waveguide optically coupled to the radiation source to transmit radiation from the source to the skin, said waveguide having two opposed surfaces and a sidewall extending between said surfaces,

20 a detector coupled to the waveguide to detect at least a portion of radiation backscattered from a skin region illuminated by the source radiation, and

25 an optical contact sensor optically coupled to said sidewall, said sensor determining whether said waveguide is in contact with the skin based on detection of backscattered radiation leaking through said sidewall.

47. A dermatological device, comprising:  
30 a radiation source assembly;

a first waveguide having a proximal end adapted to receive radiation from the radiation source assembly and a distal end adapted to transmit radiation to a tissue;

5        a second waveguide having a distal end adapted to receive backscattered radiation from said first waveguide and a proximal end adapted to transmit said backscattered radiation;

10      a detector optically coupled to said second waveguide and configured to measure a physical characteristic of said tissue; and

15      a processor electrically coupled to the detector and configured to receive a signal from said detector corresponding to said backscattered radiation;

20      48. The device of claim 47, wherein the device further comprises a means for coupling said backscattered radiation exiting from said proximal end to the detector.

25      49. The device of claim 48, wherein said means comprises a beamsplitter.

30      50. The device of claim 47, wherein the radiation source assembly is capable of generating radiation at two or more wavelengths in a range of about 350 nm to about 1200 nm.

35      51. The device of claim 47, wherein the radiation source assembly is capable of generating radiation at two or more wavelengths in a range of about 600 nm to about 900 nm.

40      52. The device of claim 47, wherein the first waveguide is an optical fiber.

53. The device of claim 47, wherein the second waveguide is an optical fiber.

5 54. The device of claim 47, further comprising additional waveguides

55. The device of claim 54, wherein said additional waveguides are optical fibers.

10 56. A dermatological device, comprising

at least one source of radiation,

an optical fiber receiving radiation from said source at a proximal end

15 and applying the radiation to a skin region at a distal end,

another optical fiber coupled at a distal end to skin at another region separated from the illuminated region by a skin segment so as to receive at least a portion of the applied radiation after transmission through that segment,

20 a detector optically coupled to a proximal end of said another optical fiber to detect at least a portion of said transmitted radiation received by that fiber, said detector generating a signal indicative of an intensity of said received radiation, and

25 a processor operating on said detector signal to determining a skin characteristic.

30 57. A method of determining a characteristic of tissue comprising:

applying radiation of first and second wavelengths from a waveguide to said tissue;

detecting at least a portion of radiation of said first and second wavelengths backscattered from said tissue

generating at least one signal indicative of an intensity of the 5 backscattered radiation, and

processing said at least one signal to calculate a characteristic of the skin region.

10 58. The method of claim 57, wherein the step of applying radiation further comprises applying radiation at a plurality of wavelengths selected from a range of about 350 nm to about 1200 nm, to the skin.

15 59. The method of claim 57, wherein the step of applying radiation further comprises applying radiation at a plurality of wavelengths selected from a range of about 600 nm to about 900 nm.

60. The method of claim 57, further comprising detecting optical contact between the waveguide and the skin region.

20

61. The method of claim 57, further comprising sensing contact of said waveguide with said tissue by detecting a level of said backscattered radiation.

25 62. The method of claim 57, further comprising reducing ambient radiation to prevent its detection by the detector.

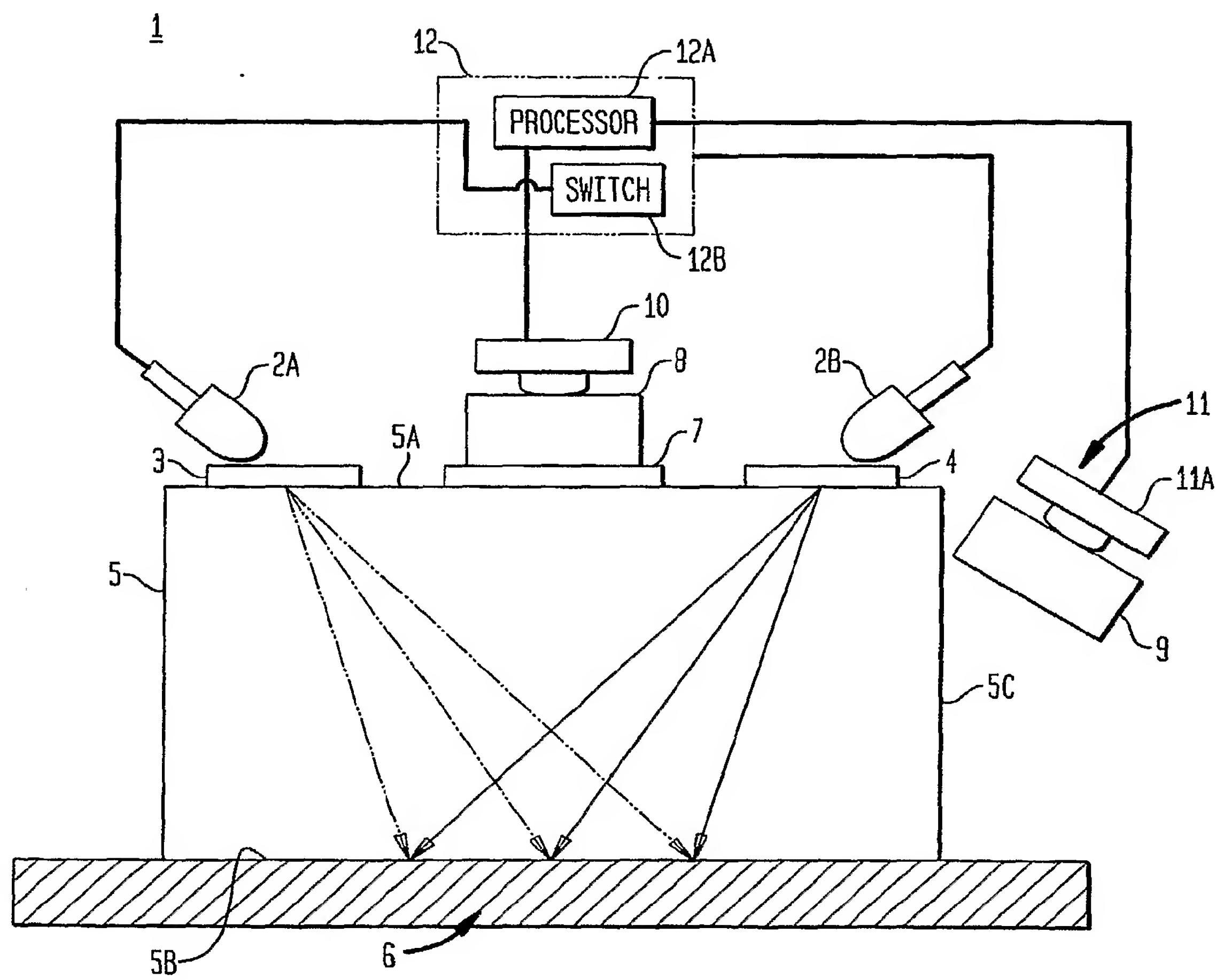
63. The method of claim 64, further comprising:

reducing radiation having a first polarity prior to detection; and

30

detecting radiation having a second polarity.

FIG. 1A



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2/17

FIG. 1B

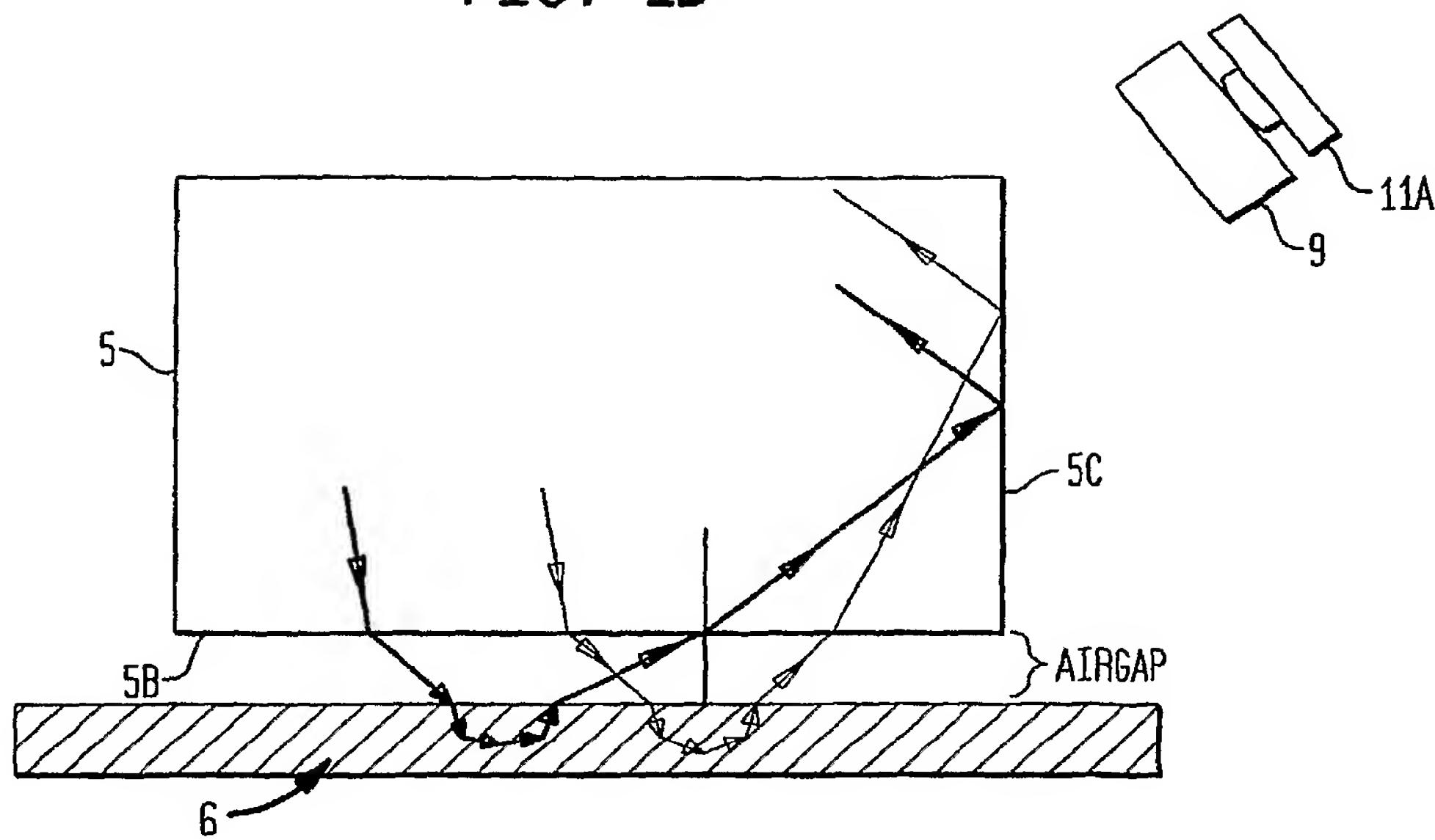
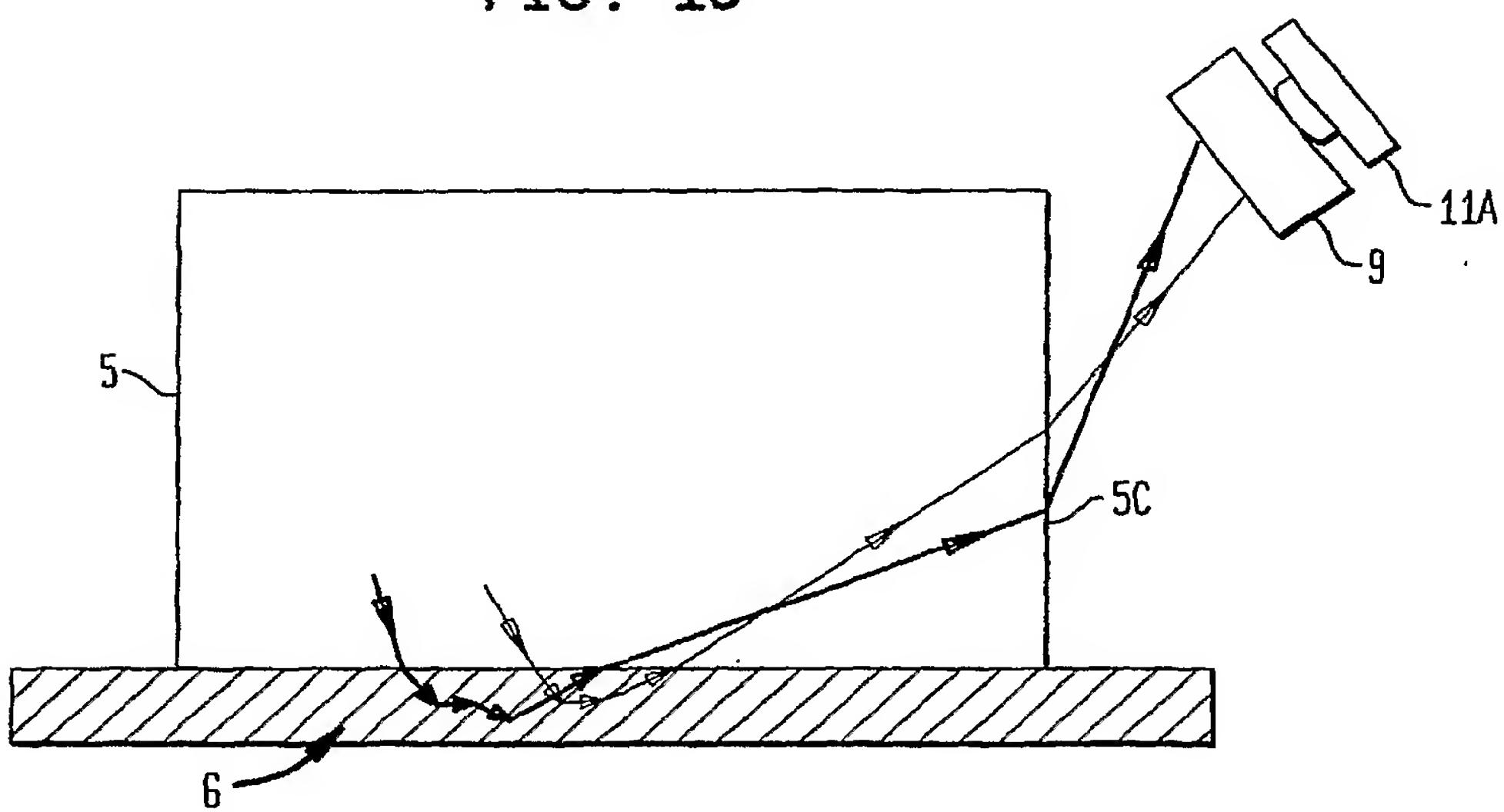
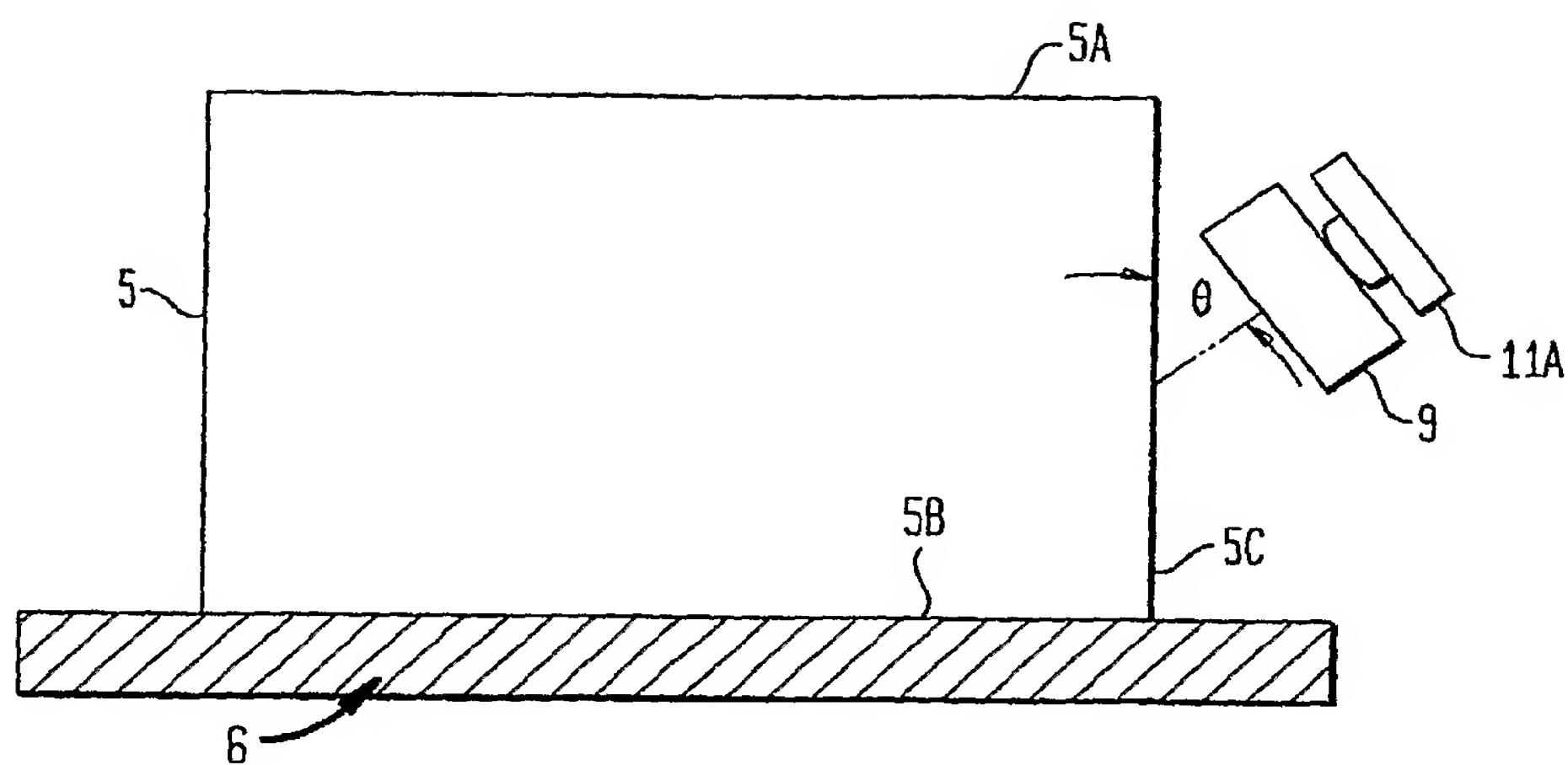
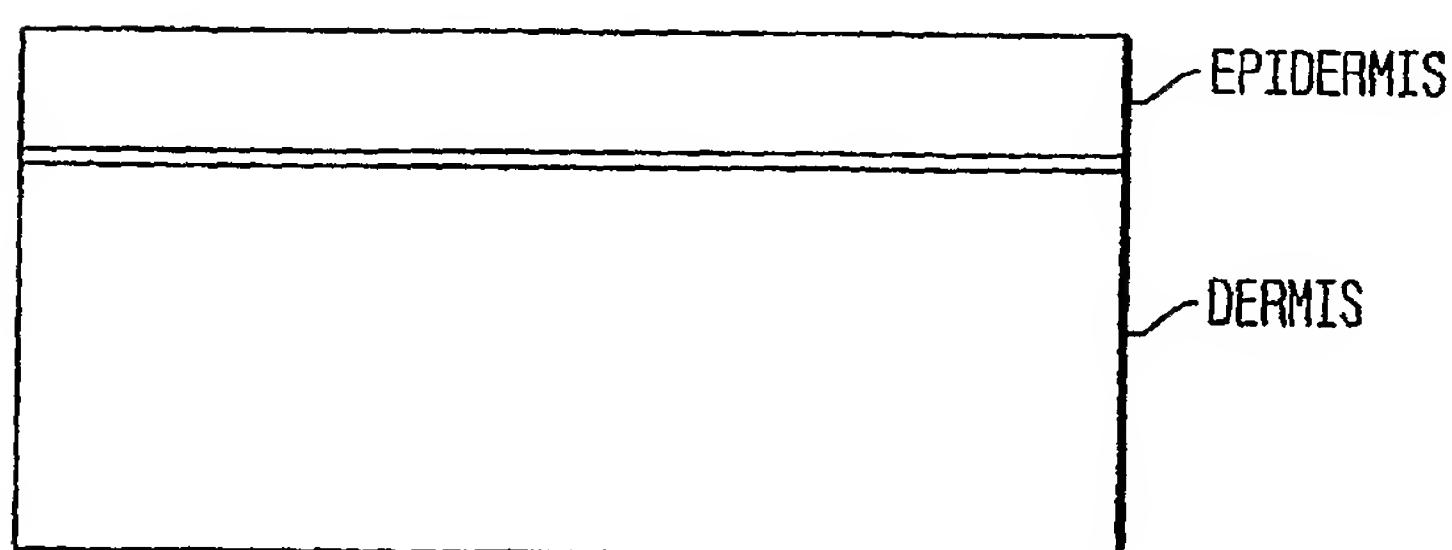


FIG. 1C



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3/17

**FIG. 1D****FIG. 1E****SUBSTITUTE SHEET (RULE 26)**

4/17

FIG. 1F

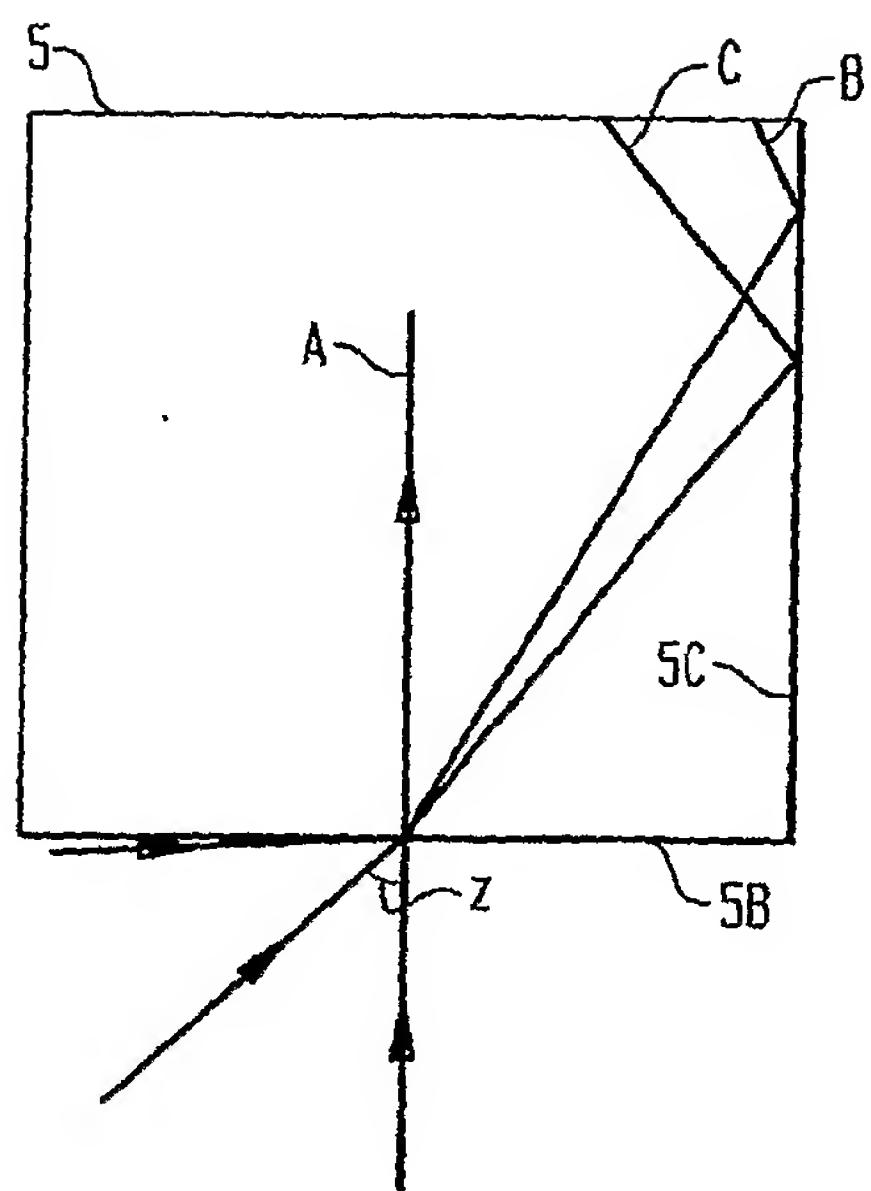
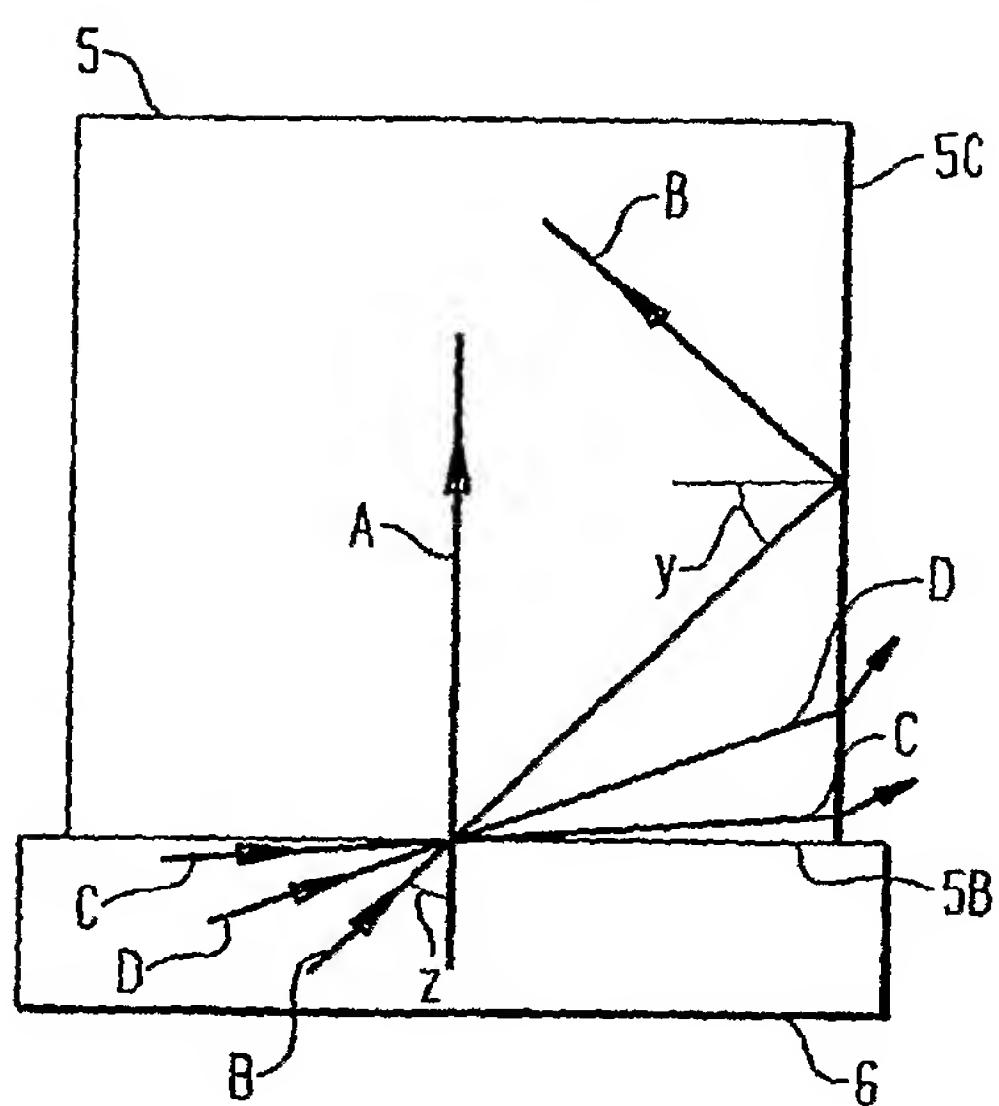


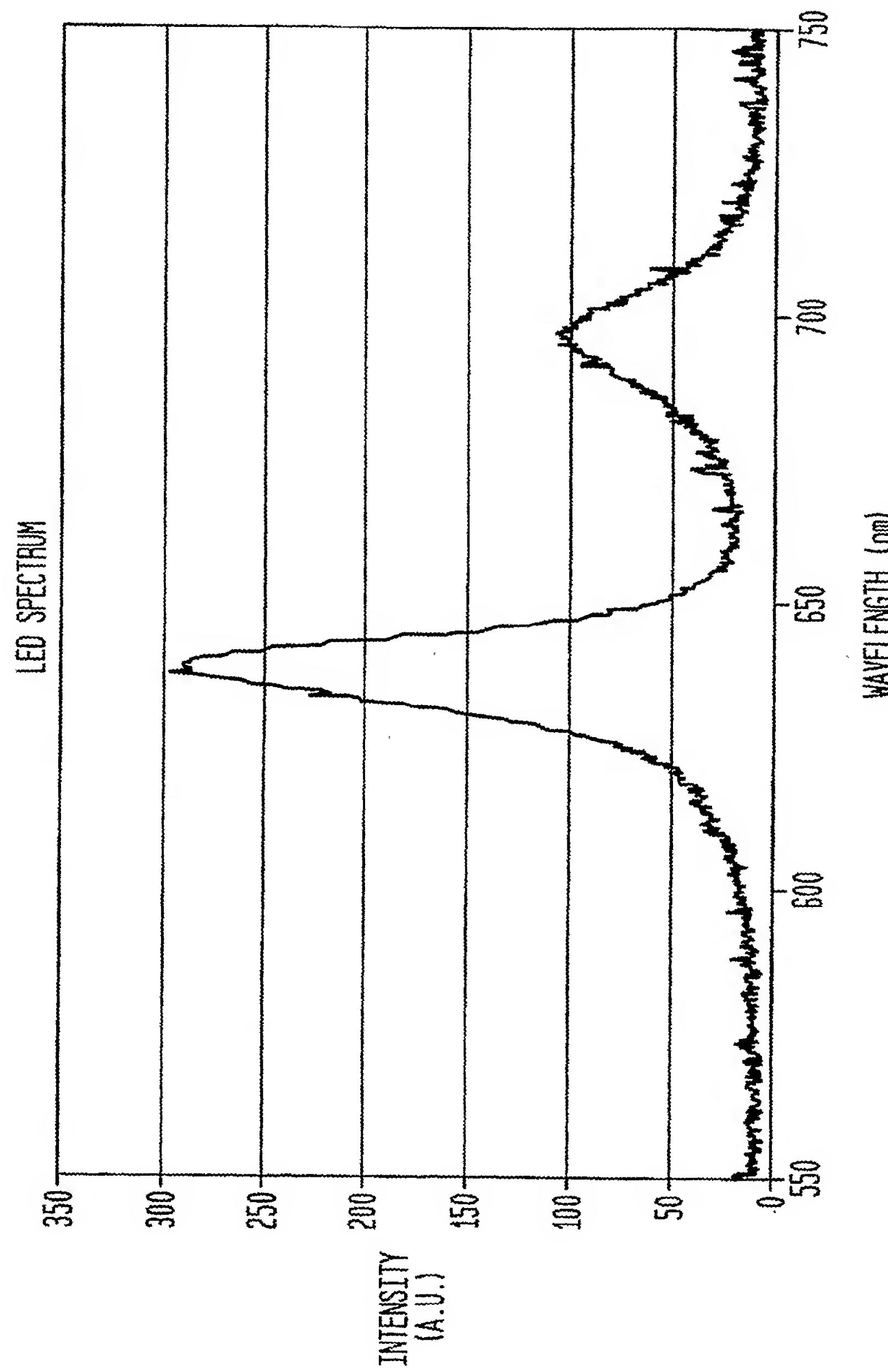
FIG. 1G



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5/17

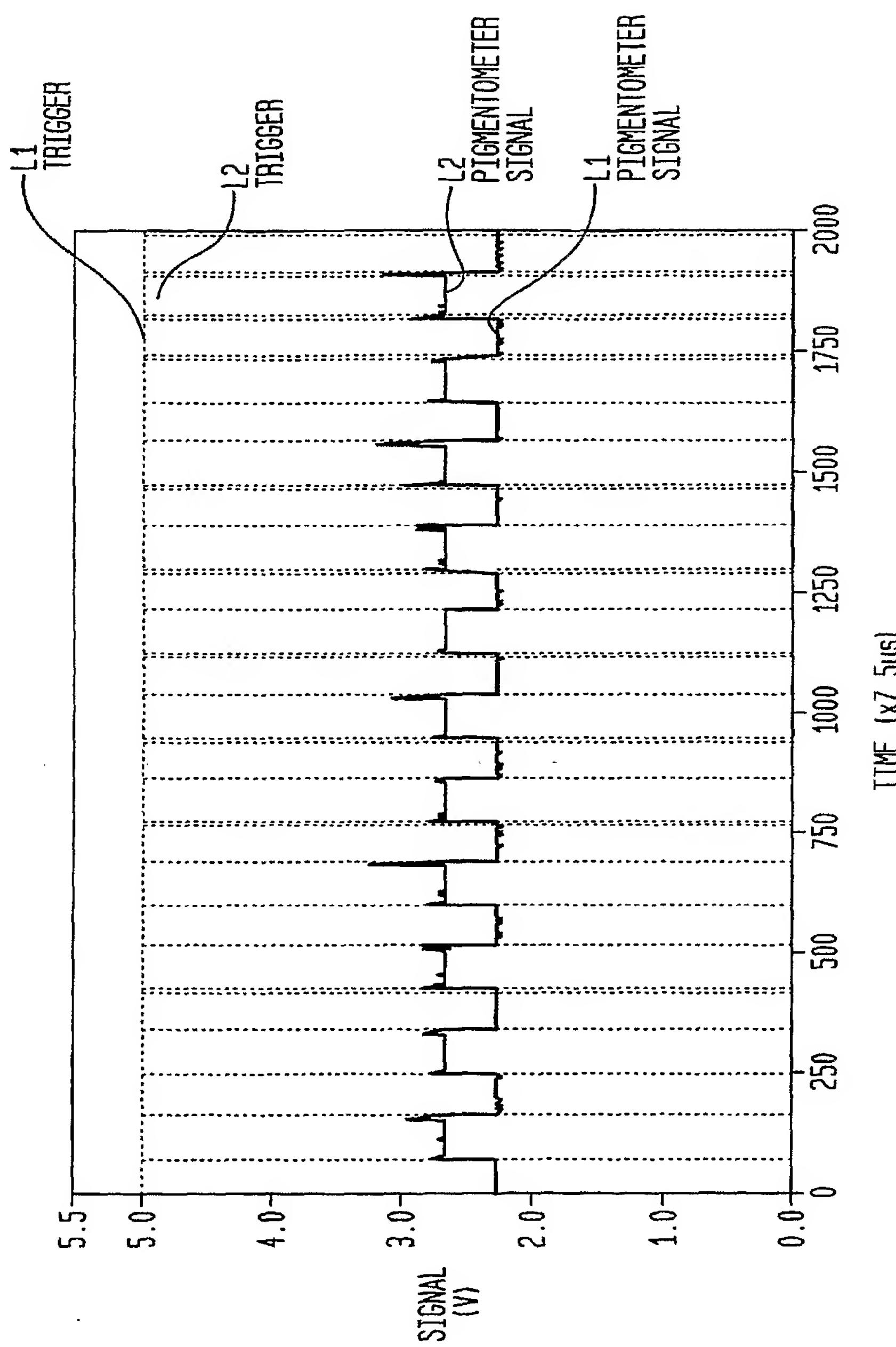
**FIG. 2**  
LED 1 AND 2



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6/17

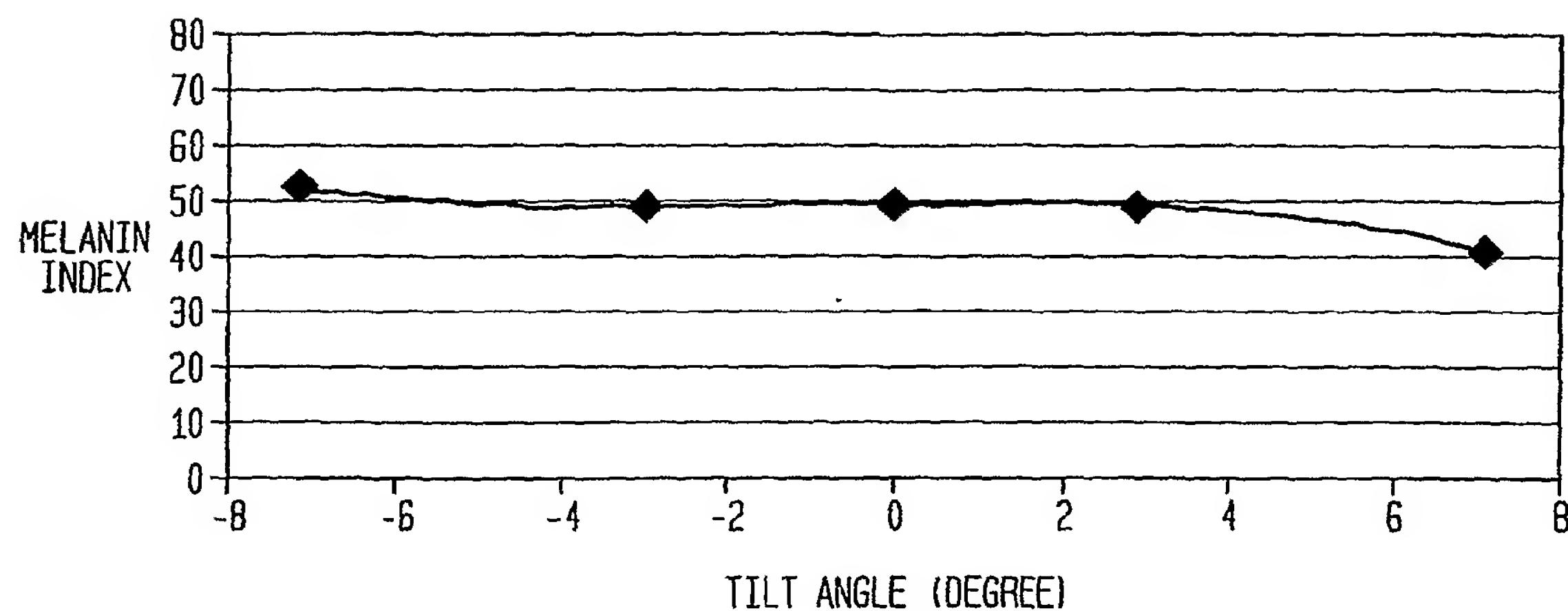
**FIG. 3**  
RAW PIGMENTOMETER SIGNAL



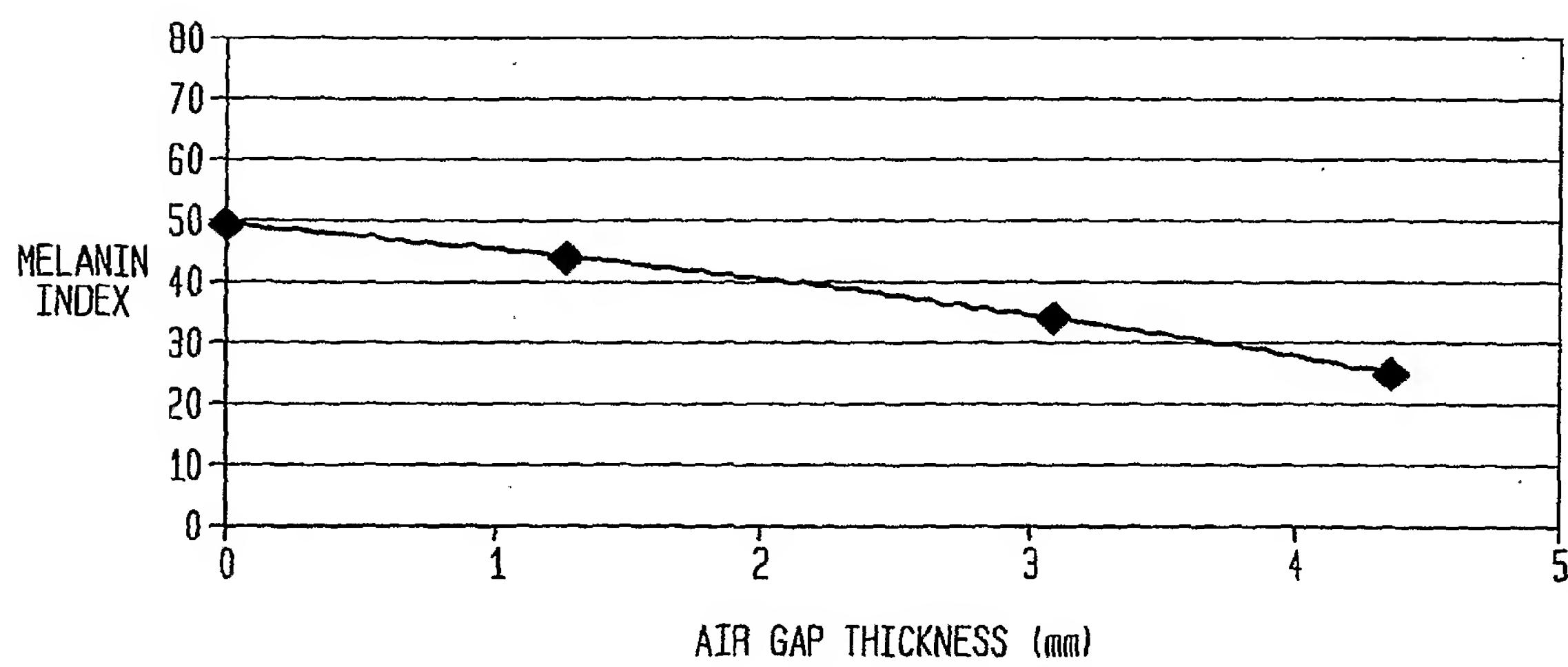
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7/17

**FIG. 4**  
ROCKING SENSITIVITY (660 vs 910 nm)

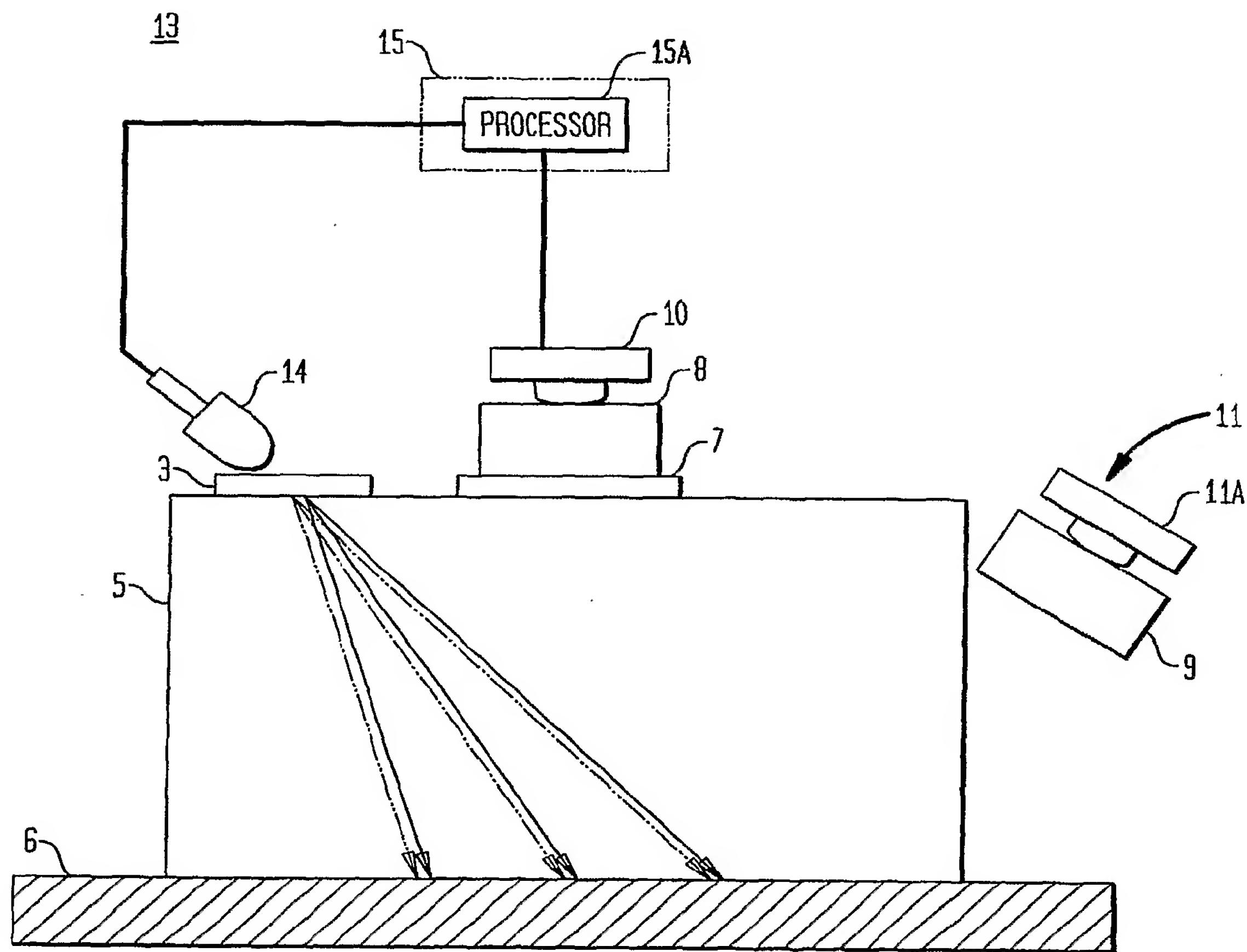


**FIG. 5**  
AIR GAP SENSITIVITY (660 vs 910 nm)



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FIG. 6



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9/17

FIG. 7A

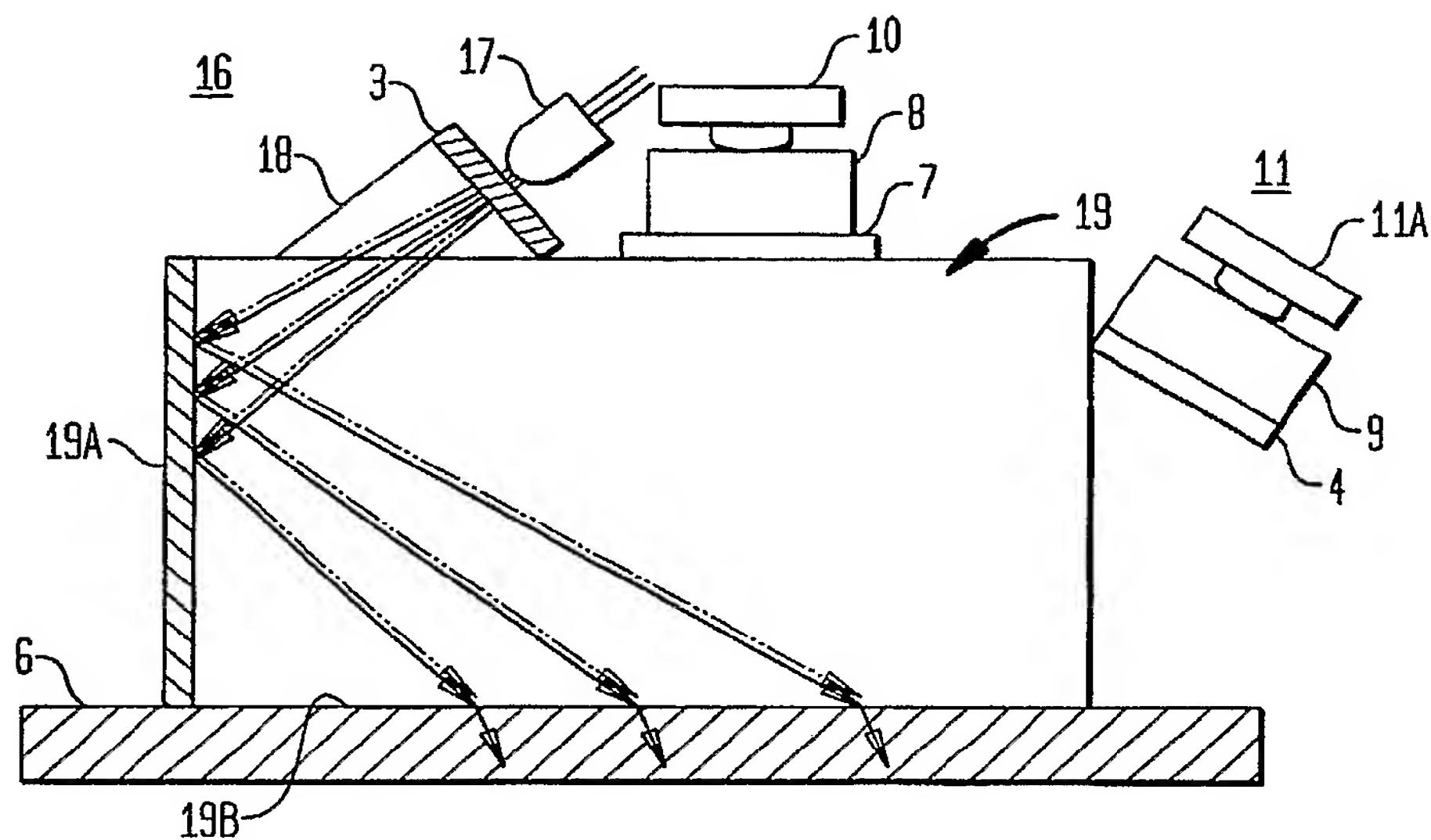
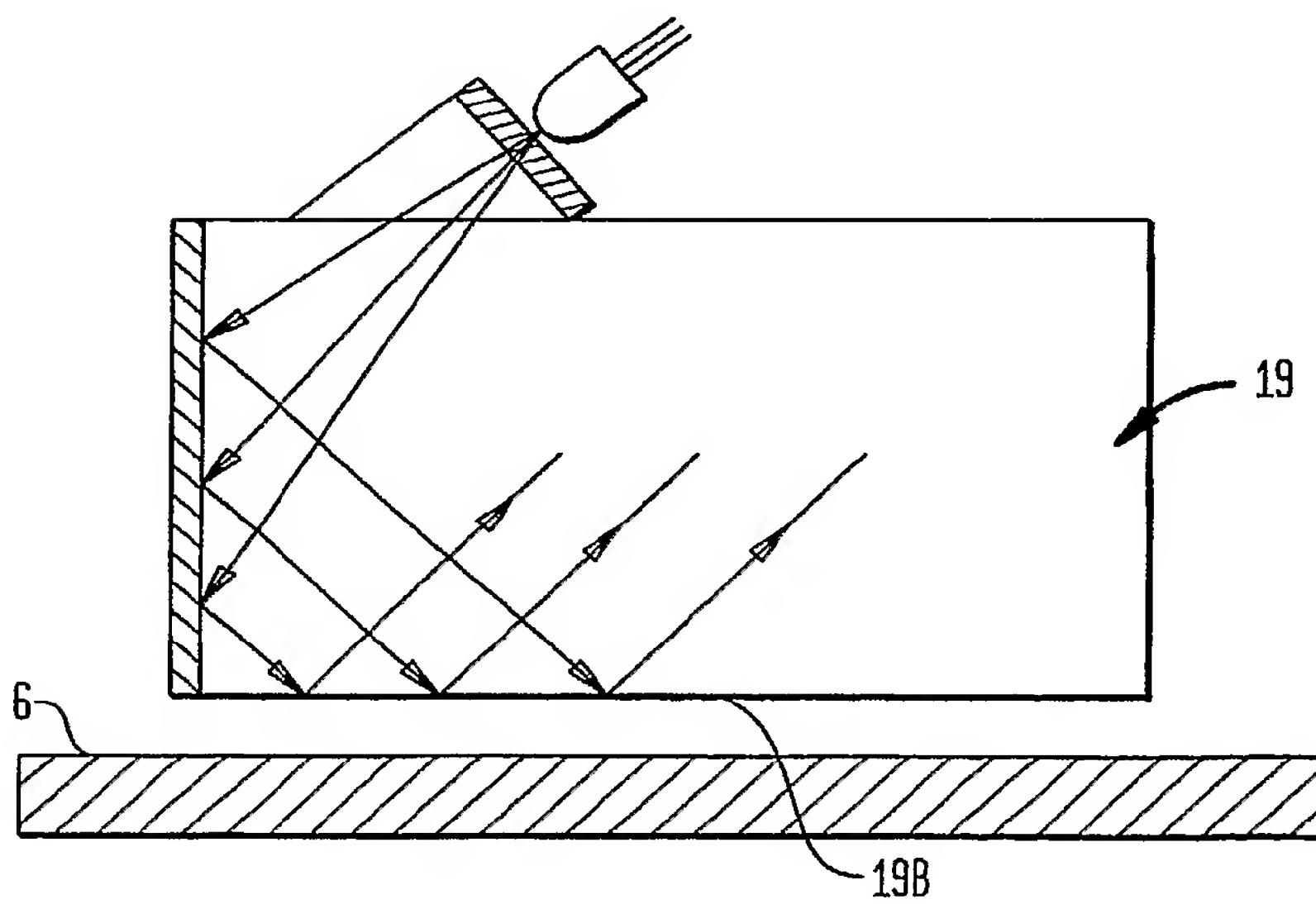
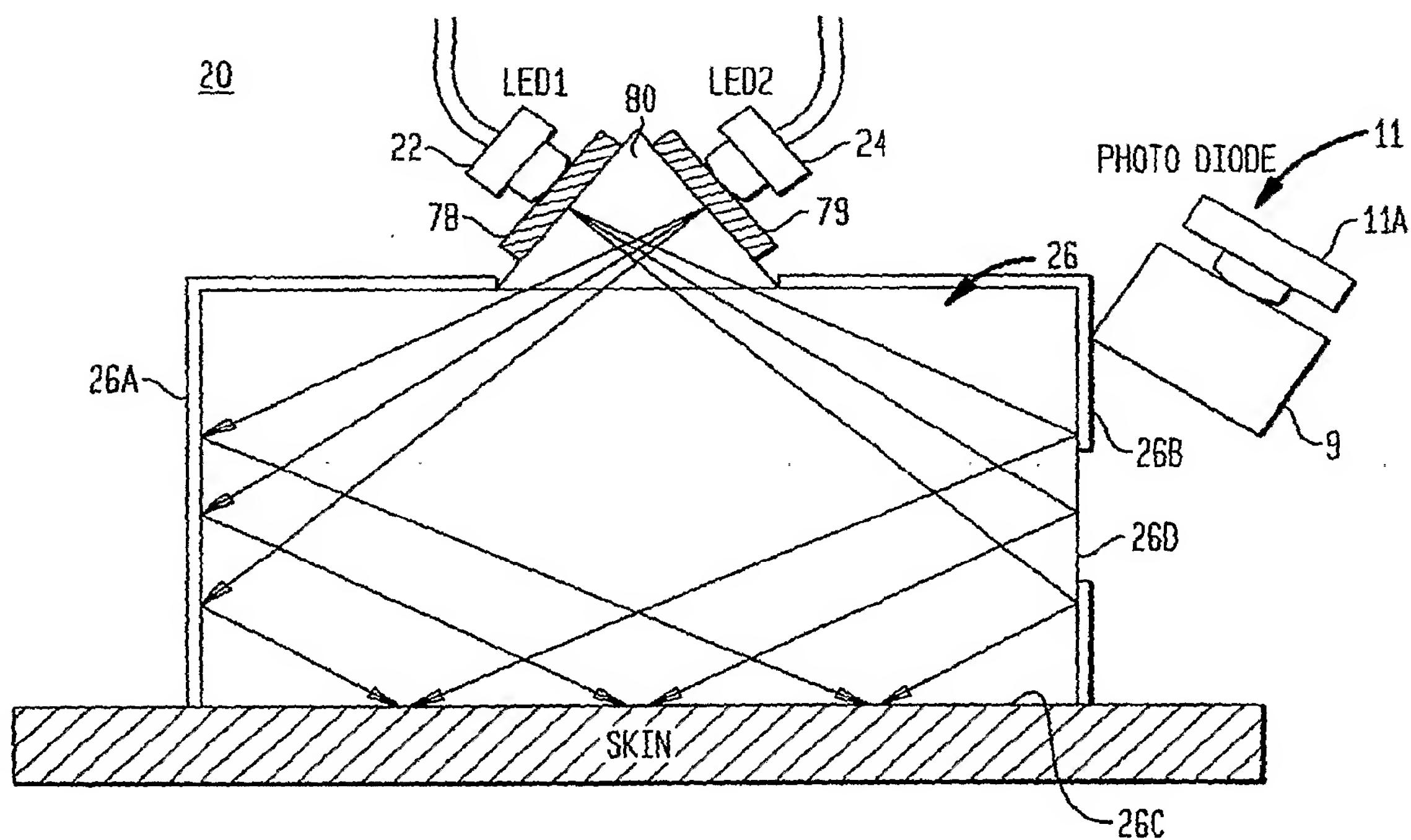


FIG. 7B

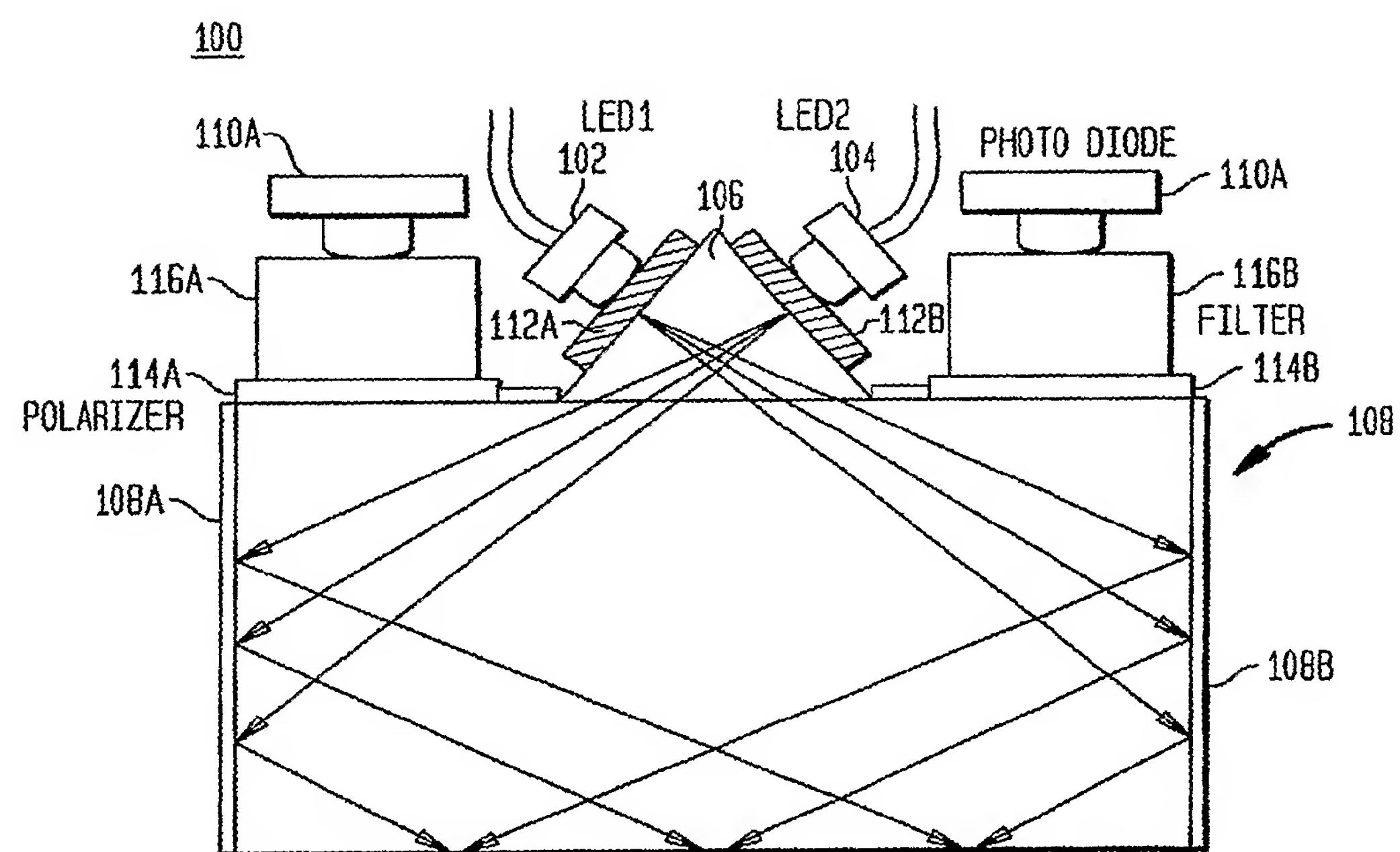


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**FIG. 8A**  
TIR COUPLING AND TIR DECOUPLING DESIGN



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**FIG. 8B****SUBSTITUTE SHEET (RULE 26)**

12/17

FIG. 9

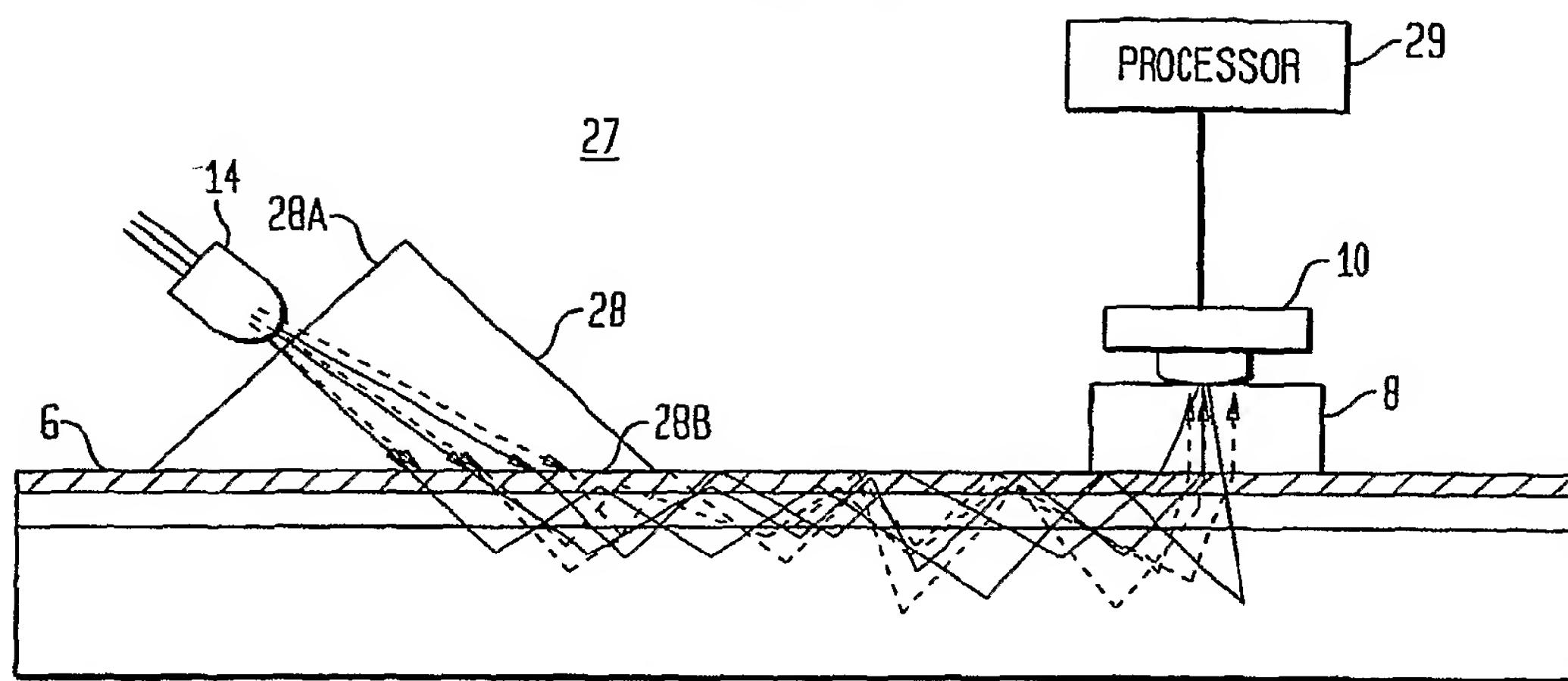
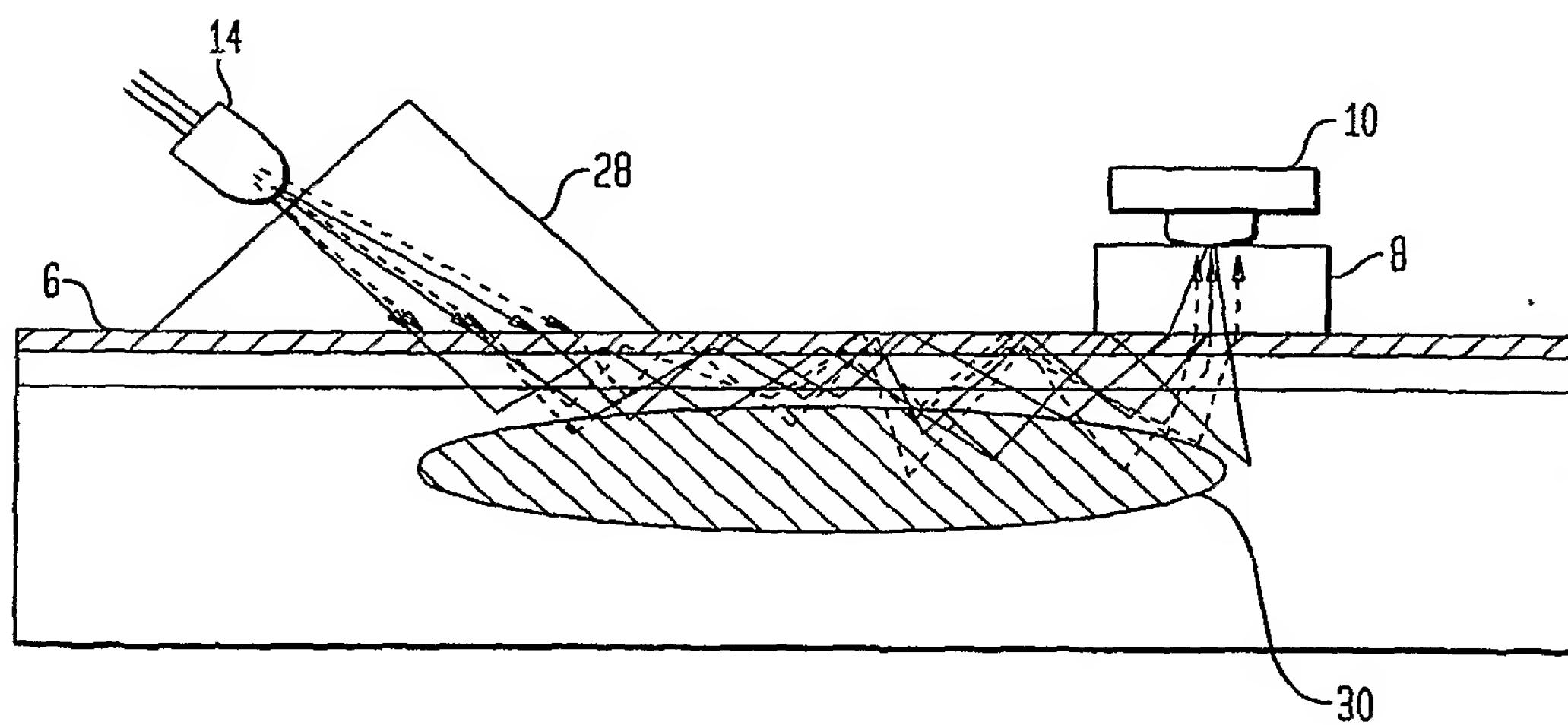
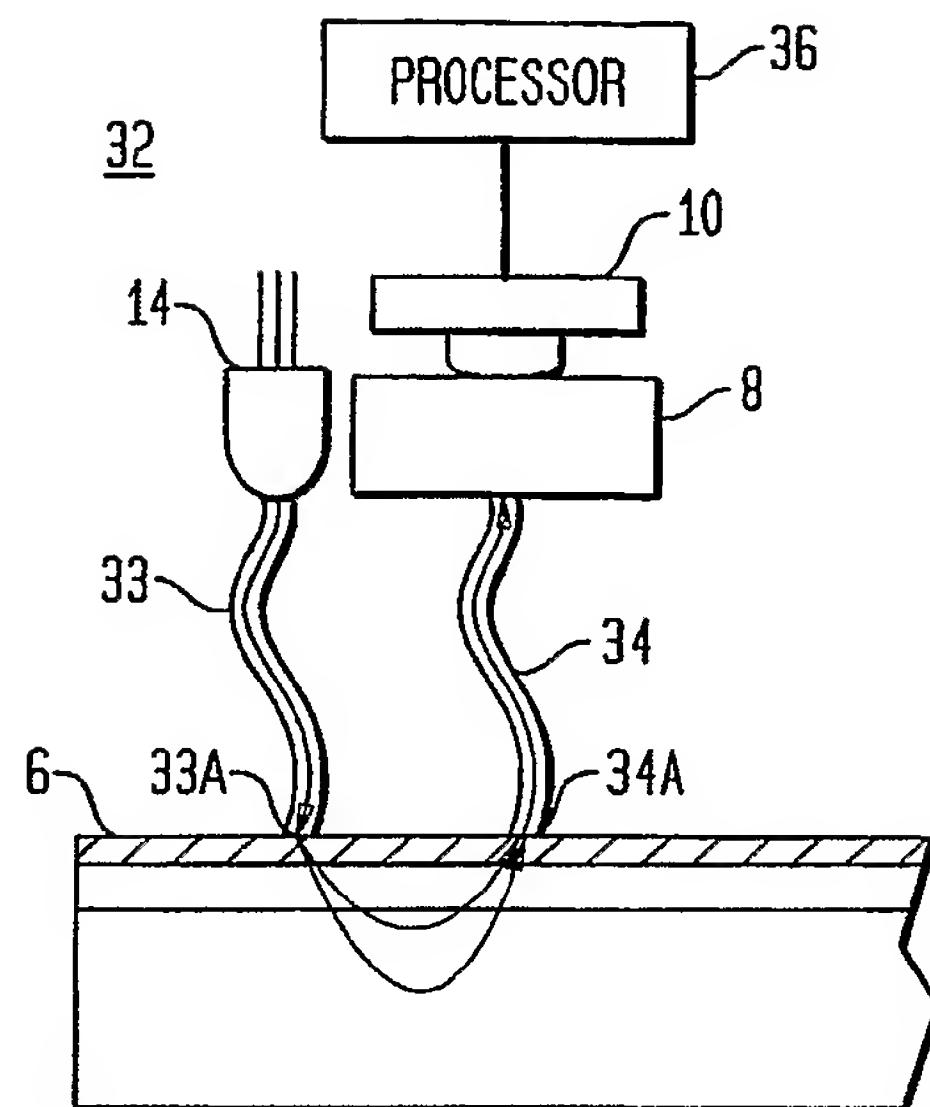
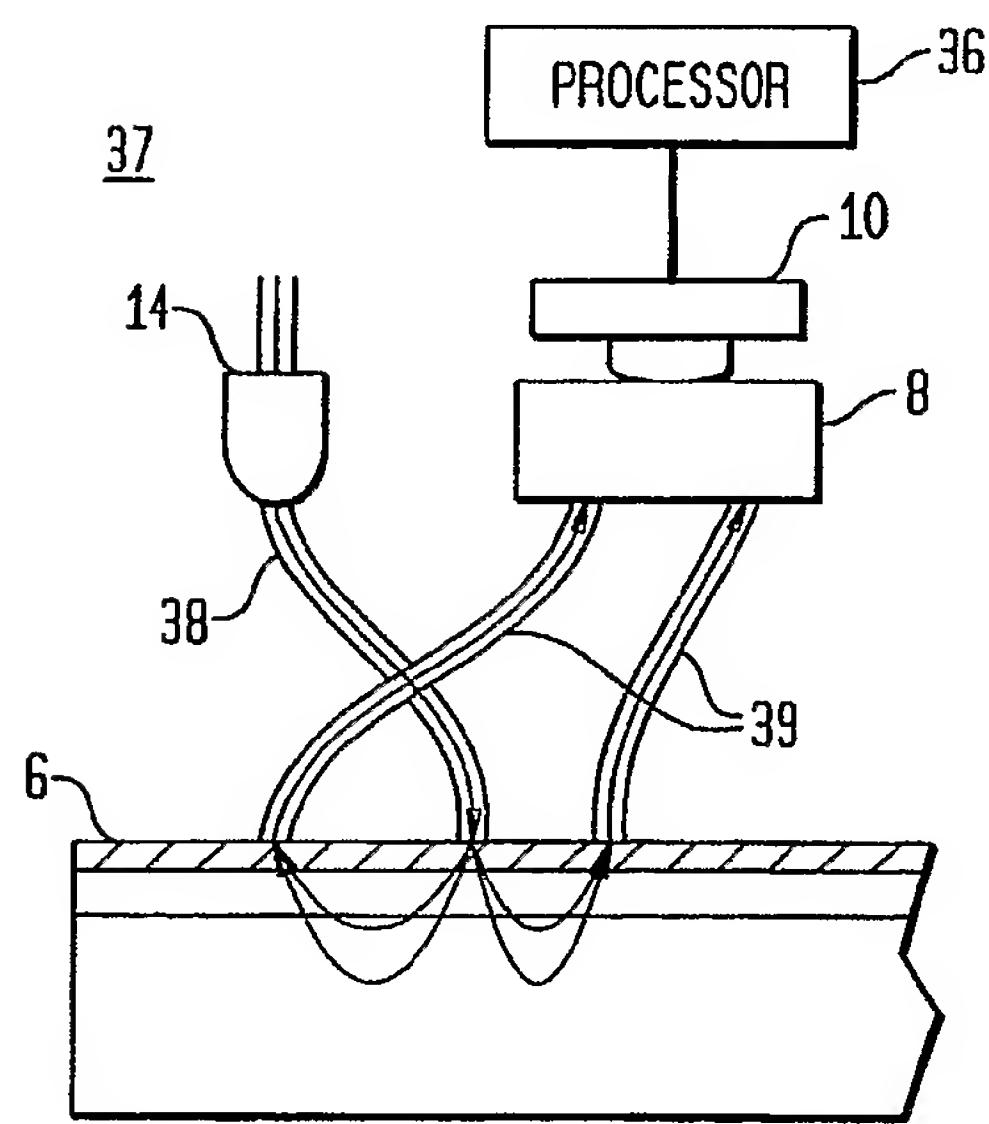


FIG. 10

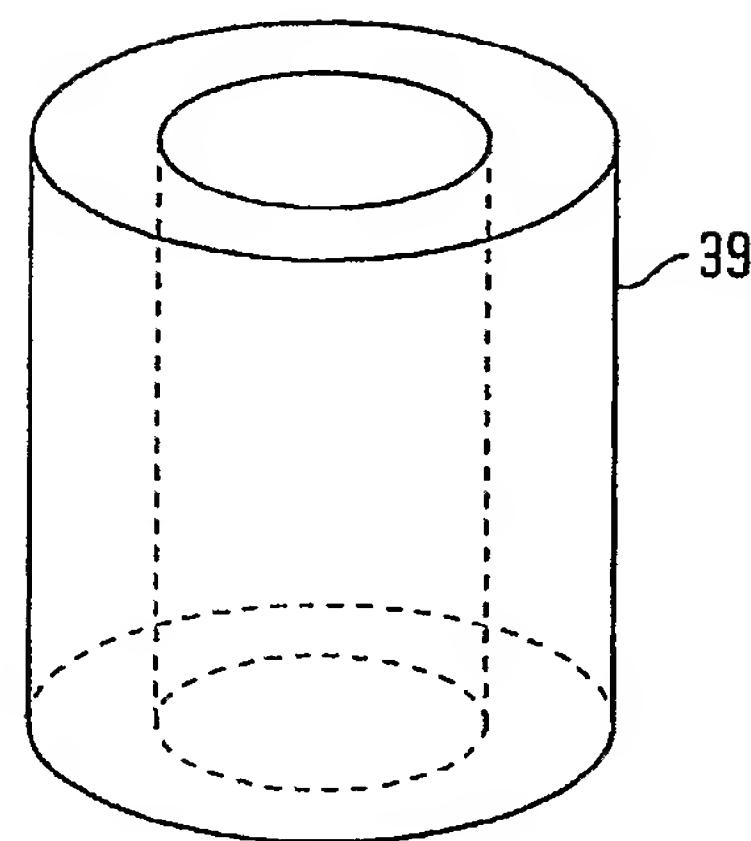
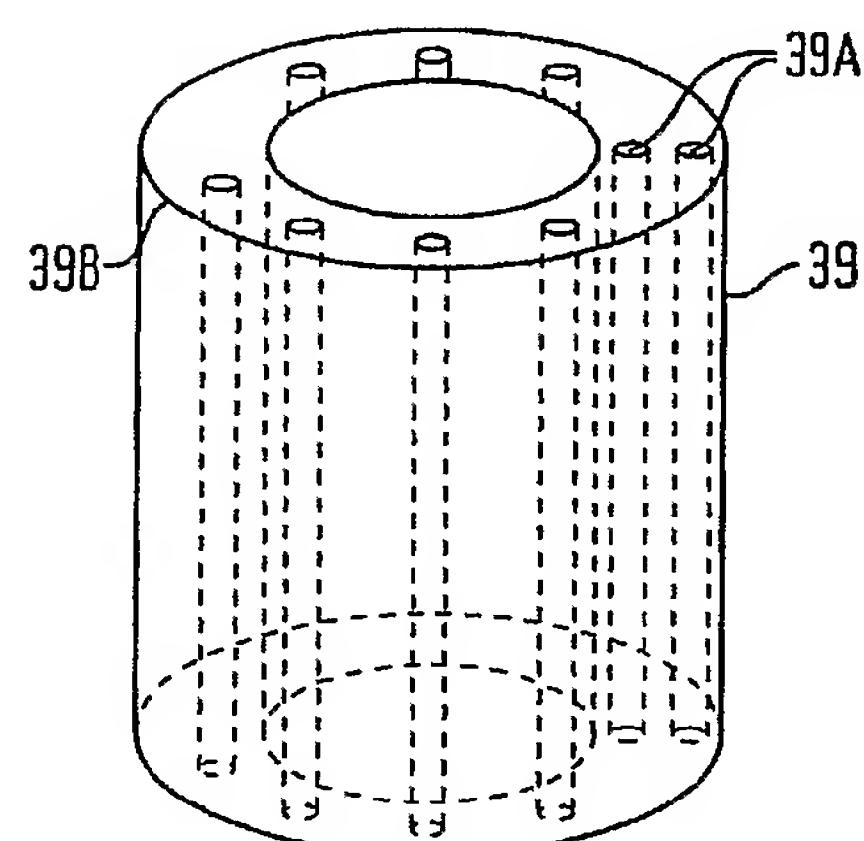


SUBSTITUTE SHEET (RULE 26)

13/17

**FIG. 11A****FIG. 11B****SUBSTITUTE SHEET (RULE 26)**

14/17

*FIG. 11C**FIG. 11D***SUBSTITUTE SHEET (RULE 26)**

15/17

FIG. 11E

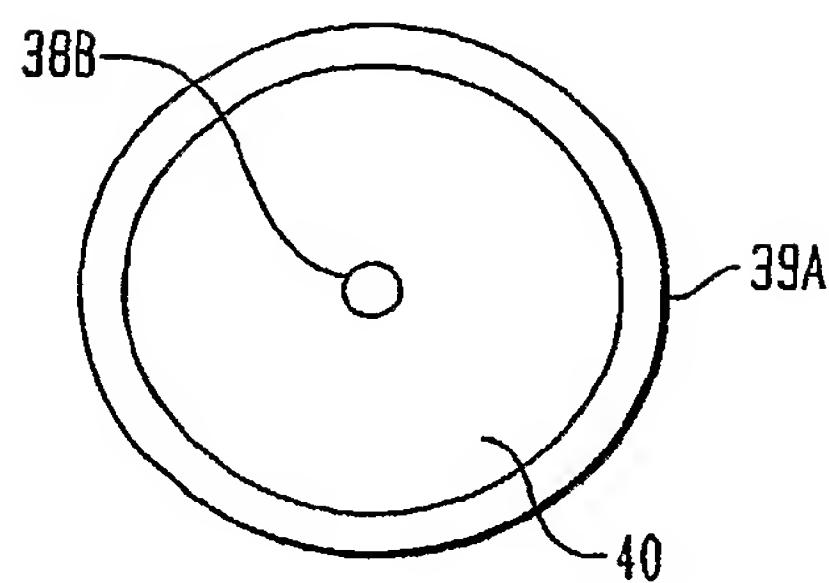
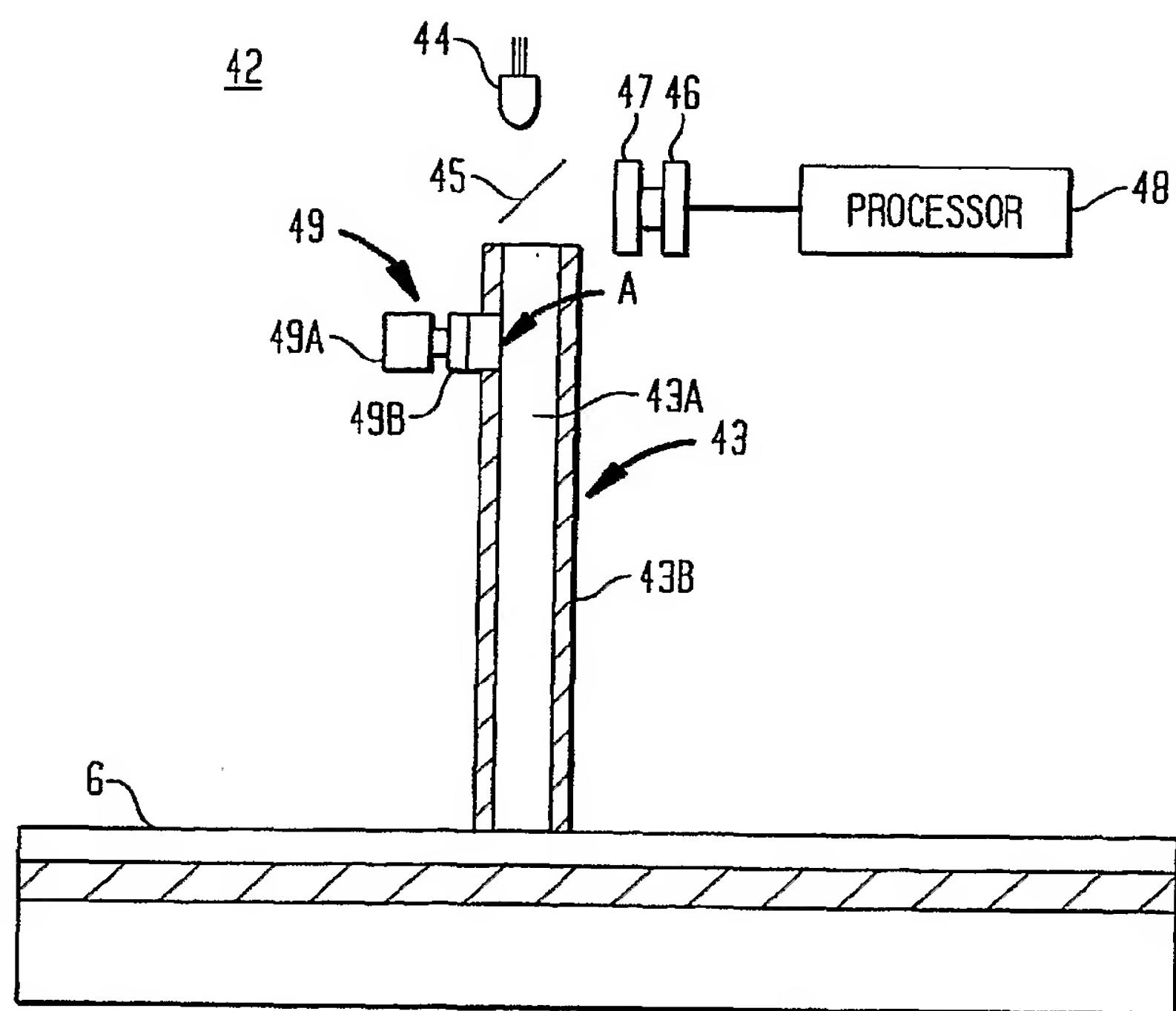


FIG. 12



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16/17

FIG. 13

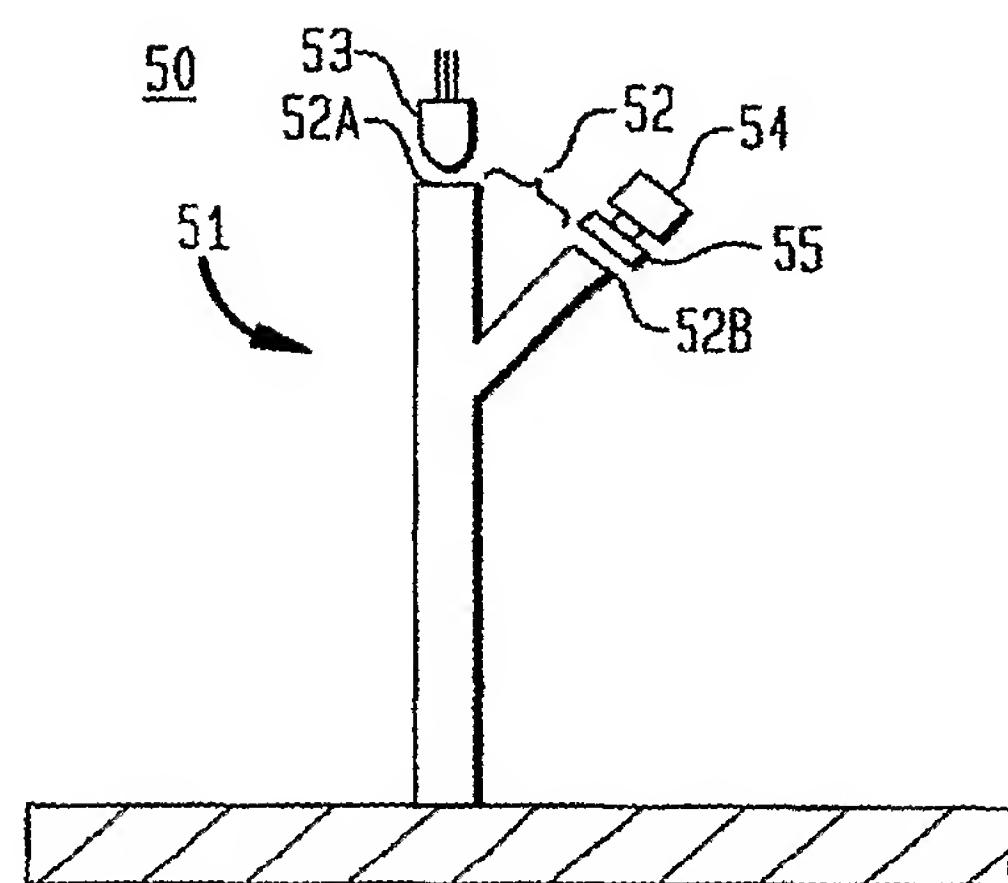
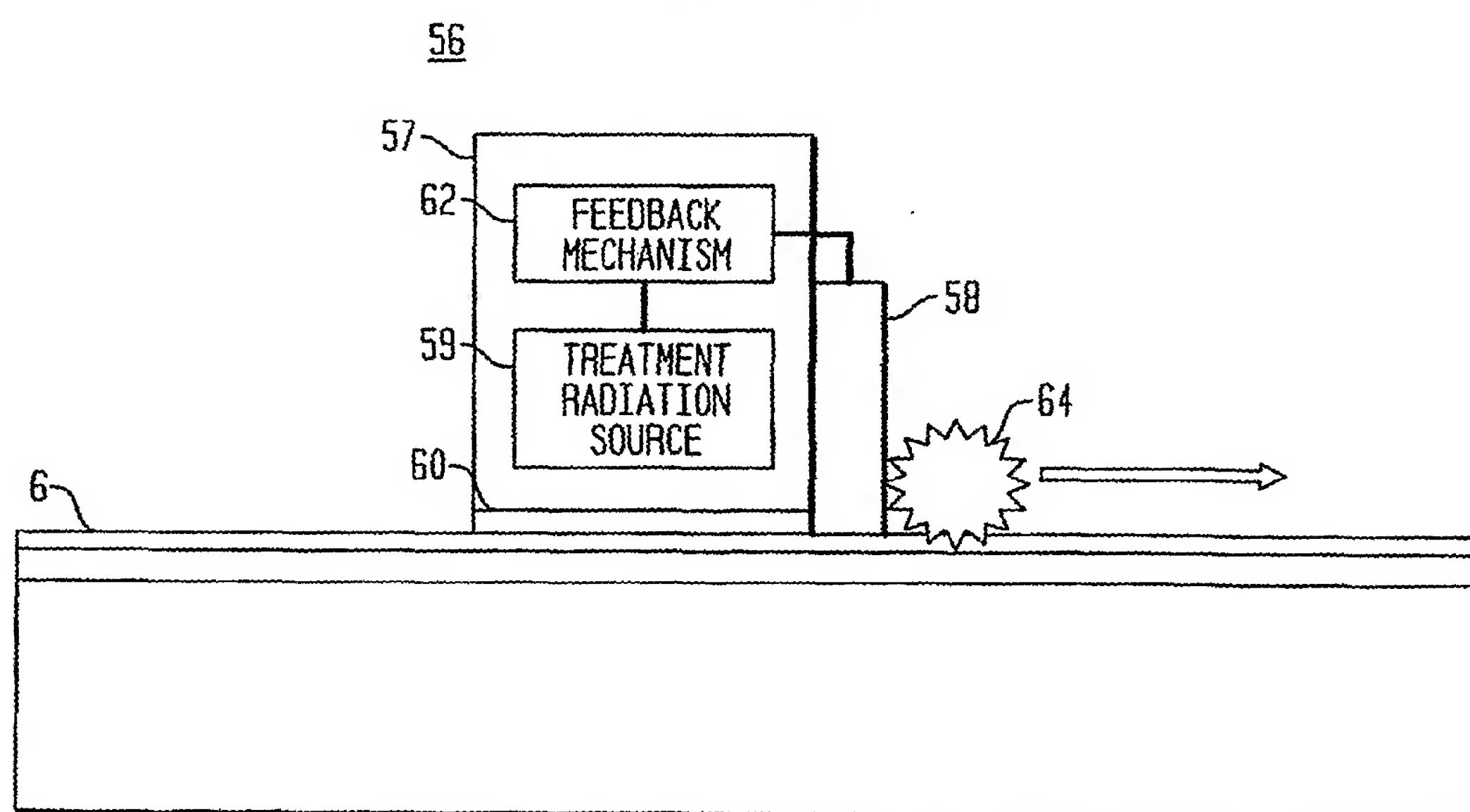
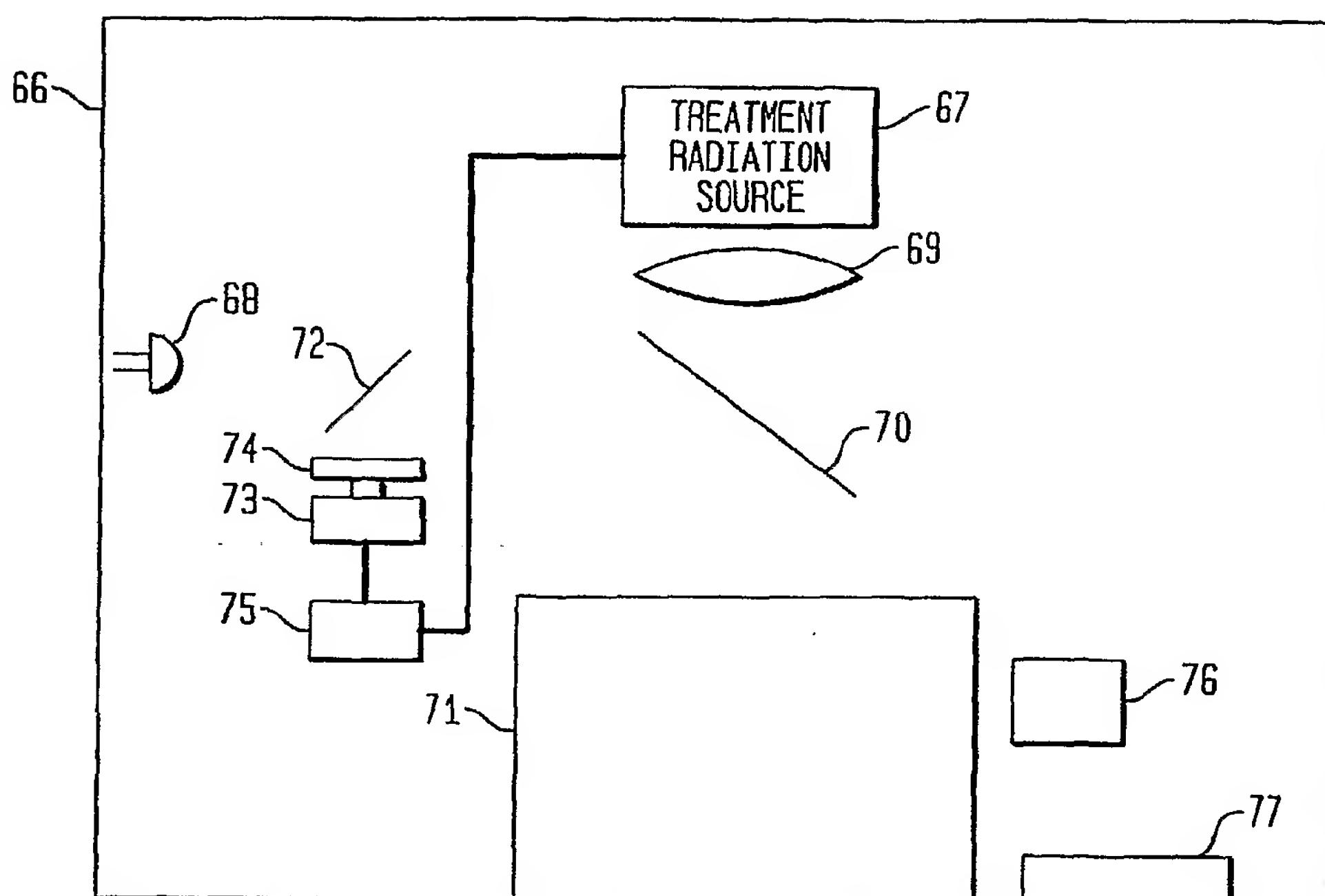


FIG. 14



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FIG. 15

65**SUBSTITUTE SHEET (RULE 26)**